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THE IMPACT OF EDUCATIONAL INTERVENTION ON THE USE OF METERED DOSE INHALER IN ASTHMATIC CHILDREN (6-18 YEARS) USING AL-WORAFI CRITERIA

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LIST OF ABBREVIATIONS

1. ACTH – Adrenocorticotropic Hormone
2. Al-Worafi Criteria – A standard for assessing correct MDI technique
3. AOR – Adjusted Odds Ratio
4. ATS – American Thoracic Society
5. CD14 – Cluster of Differentiation 14
6. CI – Confidence Interval
7. CNS – Central Nervous System
8. CRH – Corticotropin-Releasing Hormone
9. CRS – Chronic Respiratory Symptoms (or Condition, depending on context)
10. DEFF – Design Effect
11. Der f I – Dermatophagoides farinae (Dust Mite Allergen)
12. Der p I – Dermatophagoides pteronyssinus (Dust Mite Allergen)
13. DPI – Dry Powder Inhaler
14. Eosinophil – A type of white blood cell involved in allergic reactions
15. EPR2 – Expert Panel Report 2
16. ERS – European Respiratory Society
17. FEV1 – Forced Expiratory Volume in 1 second
18. FEV1/FVC – Forced Expiratory Volume in 1 second / Forced Vital Capacity
19. GM-CSF – Granulocyte-Macrophage Colony-Stimulating Factor
20. GINA – Global Initiative for Asthma
21. HFA – Hydrofluoroalkane
22. HIV – Human Immunodeficiency Virus
23. HPA Axis – Hypothalamic-Pituitary-Adrenal Axis
24. HPA – Hypothalamic-Pituitary-Adrenal (Axis)
25. ICS – Inhaled Corticosteroids
26. IFN – Interferon
27. IL – Interleukin
28. IgE – Immunoglobulin E

29. ISAAC – International Study of Asthma and Allergies in Childhood
30. LABA – Long-Acting Beta-Agonist
31. MDI – Metered Dose Inhaler
32. NAEPP – National Asthma Education and Prevention Program
33. NGF – Nerve Growth Factor
34. NIH – National Institutes of Health
35. NP – Number of Patients
36. OPD – Outpatient Department
37. OR – Odds Ratio
38. PEFR – Peak Expiratory Flow Rate
39. pMDI – Pressurized Metered Dose Inhaler
40. QoL – Quality of Life
41. SABA – Short-Acting Beta-Agonist
42. SD – Standard Deviation
43. SP – Substance P
44. SPSS – Statistical Package for the Social Sciences
45. SARS-CoV-2 – Severe Acute Respiratory Syndrome Coronavirus 2
46. Th1 – Type 1 T-helper cells
47. Th2 – Type 2 T-helper cells
48. TNF – Tumor Necrosis Factor
49. TGF – Transforming Growth Factor
50. VIP – Vasoactive Intestinal Peptide
51. d – Desired Precision or Margin of Error
52. N – Total Population Size
53. p – Proportion of the population with the characteristic of interest
54. HSV-1 – Herpes Simplex Virus 1
55. EBV – Epstein-Barr Virus

INTRODUCTION

INTRODUCTION

Asthma is a chronic inflammatory disease of the airways that is characterized by hyper-reactivity of the airways resulting in bronchial obstruction. This condition leads to recurring symptoms such as wheezing, breathlessness, chest tightness, and coughing, particularly at night or early in the morning. It is one of the most common chronic diseases affecting children and adults worldwide, significantly impacting their quality of life. Asthma prevalence has been increasing globally, and recent statistics indicate that approximately 7.9% of children in India were affected in 2022, a rise from 7.9% in 2015 in New Delhi. In Pakistan, asthma prevalence among adults ranges from 5% to 10%, reflecting a substantial public health burden [1].

Despite advancements in the understanding and treatment of asthma, the disease continues to impose a significant global health and economic burden. Inhalation therapy remains the cornerstone of asthma management. Compared to systemic medication delivery, inhalation therapy has several advantages, including minimal systemic side effects, direct delivery to the site of action in the lungs, and quicker therapeutic outcomes. According to the European Respiratory Society (ERS) and the American Thoracic Society (ATS) guidelines, the first-line treatment for asthma includes the use of inhaled bronchodilators and corticosteroids [2].

MDIs are widely recognized for their benefits, including minimal side effects, enhanced lung deposition, cost-effectiveness, and portability. However, the efficacy of MDIs depends heavily on the correct usage technique. Incorrect inhaler technique has been identified as a major contributor to treatment failure in asthmatic patients. Studies have shown that poor inhaler technique can lead to suboptimal drug delivery, resulting in persistent symptoms, frequent exacerbations, and increased hospitalizations. This not only affects the patient's health but also imposes an economic burden on families and healthcare systems worldwide [3].

Education and proper training in the use of MDIs are crucial for optimal asthma management. Kishore et al. (2008) in Nepal reported that patients without proper guidance were five times more likely to use their inhalers incorrectly [4]. This highlights the critical role of healthcare providers in educating patients and caregivers

about proper inhaler techniques. Inadequate instructions or the absence of guidance from healthcare professionals often leads to inappropriate MDI use, which is a significant barrier to effective asthma management [5].

While MDIs are highly effective when used correctly, studies indicate that a large proportion of asthmatic patients lack the knowledge and skills required for proper inhaler use. The absence of structured educational interventions exacerbates this issue, leading to poor disease control and increased morbidity. Personalized education and regular monitoring of inhaler techniques are essential components of asthma management. Educational interventions should focus on empowering patients and caregivers with the necessary knowledge and skills to use MDIs effectively [6].

Several studies have emphasized the importance of educational interventions in improving inhaler techniques and asthma control. For instance, research has demonstrated that targeted education programs can significantly enhance patients' ability to use inhalers correctly, resulting in better disease outcomes. However, there remains a scarcity of studies focusing on educational interventions specifically tailored for children with asthma and their caregivers [7].

Asthma management in children presents unique challenges. Children rely heavily on their caregivers for medication administration, making it imperative to educate both the child and the caregiver. Additionally, children’s understanding and adherence to treatment regimens may vary depending on their age, cognitive ability, and level of supervision. Addressing these challenges requires a comprehensive approach that includes age-appropriate education and training [8].

The Al-Worafi criteria provide a framework for evaluating the impact of educational interventions on inhaler technique and asthma outcomes. This criterion emphasizes the need for structured, evidence-based educational programs that are tailored to the specific needs of patients. By applying the Al-Worafi criteria, healthcare providers can systematically assess and improve the effectiveness of educational interventions, ensuring that patients receive the highest standard of care [9].

Studies have shown that educational interventions can reduce asthma-related morbidity and mortality by improving inhaler technique, enhancing medication

adherence, and promoting better symptom control. For example, a study conducted by a multidisciplinary team in the United Kingdom demonstrated that a structured educational program improved inhaler technique in over 80% of participants, leading to a significant reduction in hospital admissions and emergency room visits [10].

Inhaler technique education should be an integral part of asthma management. It is essential to provide patients with personalized information and hands-on training to ensure they can use their inhalers correctly. Regular monitoring and reinforcement of inhaler technique are also crucial to maintain optimal asthma control. Healthcare providers should prioritize patient education as a key component of asthma care, recognizing that effective communication and patient engagement are fundamental to achieving better health outcomes [11].

Furthermore, the economic implications of asthma management cannot be overlooked. Incorrect MDI technique leads to increased healthcare costs due to frequent hospitalizations, emergency room visits, and missed school or workdays. Educational interventions aimed at improving inhaler technique can help reduce these costs by enhancing disease control and preventing exacerbations. By investing in patient education, healthcare systems can achieve better health outcomes while reducing the economic burden associated with asthma [12].

The role of caregivers in asthma management is particularly important for children. Caregivers often play a central role in ensuring that children use their inhalers correctly and adhere to their treatment regimens. Educational interventions should therefore include caregivers as active participants, providing them with the knowledge and skills needed to support their children effectively. Empowering caregivers through education can significantly improve asthma outcomes in children and enhance their quality of life [13].

Despite the proven benefits of educational interventions, several barriers hinder their implementation. These include limited access to healthcare resources, lack of trained personnel, and insufficient time during clinical consultations. Addressing these barriers requires a coordinated effort from healthcare providers, policymakers, and community organizations. Strategies such as telehealth consultations, community-

based education programs, and school-based asthma management initiatives can help overcome these challenges and ensure that patients receive the education they need [14].

The use of technology in asthma education has gained significant attention in recent years. Mobile health (mHealth) applications, online training modules, and virtual reality tools are increasingly being used to educate patients about proper inhaler techniques. These technologies offer innovative and accessible solutions for delivering personalized education, particularly in resource-limited settings. Research has shown that mHealth interventions can significantly improve inhaler technique and asthma control, highlighting the potential of technology to enhance patient education [15].

In conclusion, asthma is a chronic inflammatory disease that significantly impacts the lives of millions of children and their families worldwide. Proper use of MDIs is essential for effective asthma management, but incorrect inhaler technique remains a major challenge. Educational interventions play a critical role in addressing this issue by empowering patients and caregivers with the knowledge and skills needed for optimal inhaler use. By applying the Al-Worafi criteria, healthcare providers can systematically evaluate and improve the effectiveness of educational programs, ensuring that patients receive the highest standard of care. Investing in patient education not only improves asthma outcomes but also reduces the economic burden associated with the disease. Moving forward, it is essential to prioritize educational interventions as a fundamental component of asthma management, leveraging innovative approaches and technology to overcome barriers and enhance patient engagement.

NEED FOR THE STUDY

Not many studies have been done in India, hence this study was planned to find the effectiveness of theoretical and practical guidance in controlling childhood asthma.

In the existing literature, non-validated and arbitrary tools have been used with unclear methodology.

Additionally, this study will focus more in the Delhi NCR region where minimal data is available in this subject.

Metered dose inhalers (MDIs) are an extremely effective tool in the control of Asthma and incorrect technique leads to treatment failure, so this study was planned to reaffirm the same and to increase the efficacy of an already efficacious treatment modality.

AIMS AND OBJECTIVES

AIMS & OBJECTIVES

Aim:

To study the Impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria[6,7,8].

Objectives:

To evaluate the technique of use of MDI device before educational intervention.

- To measure the improvement in the use of MDI after the educational intervention.
- To measure the impact on symptom control after educational intervention.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Childhood Asthma:

Global Burden of Childhood Asthma

Asthma is a prevalent disease worldwide, with its distribution varying significantly among global populations, ranging from less than 2% to approximately 33%. The global prevalence of asthma is estimated to be 200 million, with an annual mortality of approximately 0.2 million [1]. In India, the estimated burden of childhood asthma exceeds 15 million cases [2]. Asthma's control and outcomes can be influenced by coexisting allergic and non-allergic conditions.

Worldwide Trends in Asthma Prevalence: The ISAAC Phases

The International Study of Asthma and Allergies in Childhood (ISAAC)

The ISAAC initiative was established to advance research in asthma, allergic rhinoconjunctivitis, and eczema through international collaboration. Its objectives included comparing the prevalence of these conditions across different populations and time periods, as well as exploring their underlying causes [15].

Phase I: Initial Prevalence Study

In Phase I, children aged 13–14 years were studied across 155 centers in 56 countries, while children aged 6–7 years were studied at 91 centers in 38 countries. This phase revealed a 20-fold global variation in the prevalence of "current wheeze" (wheezing in the last 12 months), ranging from 1.8% to 36.7%. A sevenfold variation was noted between the 10th and 90th percentiles (4.4% to 30.9%). The highest prevalence was observed in the UK, Australia, New Zealand, and Ireland, followed by regions in North, Central, and South America. Conversely, the lowest prevalence was noted in Eastern Europe, Albania, Greece, China, Taiwan, Uzbekistan, India, Indonesia, and Ethiopia [17].

Phase II: Investigating Etiological Factors

Phase II involved an intensive investigation of potential etiological factors affecting children aged 9 to 11 years in 30 centers across 22 countries [18].

Phase III: Re-assessment and Time Trends

Phase III revisited Phase I centers after 5–10 years to:

1. Examine time trends in asthma, allergic rhinoconjunctivitis, and eczema prevalence.
2. Assess prevalence and severity in previously unexamined regions.
3. Reassess hypotheses from Phase I ecological analyses [15, 17].

Despite rigorous methodology and quality control, differences in regional trends were attributed to variability in symptom recognition and labeling. For instance, Latin America and Northern/Eastern Europe showed increased prevalence with written questionnaires but little change with video questionnaires. In contrast, the Indian subcontinent showed minimal change with written questionnaires but an increase with video questionnaires [15].

Findings from Phase III

1. **Stabilization in High-Prevalence Countries**: Many high-prevalence countries, particularly English-speaking nations, demonstrated a plateau or decline in asthma symptoms. However, exceptions included Germany and Finland, which exhibited significant increases [15].
2. **Increases in Intermediate-Prevalence Countries**: Countries such as Costa Rica, Panama, Mexico, Argentina, Chile, Ukraine, and Romania reported significant increases in prevalence [15].
3. **Increases in Low-Prevalence Countries**: With the exception of India, low-prevalence countries in Phase I reported increases in Phase III, notably in Indonesia and China, where the rise was statistically significant.

Almost all regions reported increases in lifetime asthma prevalence, even where asthma symptoms showed a decline. The "hygiene hypothesis" has been proposed as a possible explanation for increasing prevalence, though it remains insufficient to account for trends in both atopic and non-atopic asthma [20].

Neuroimmunology and Inflammation

Stress and Allergic Diseases

Stress plays a significant role in disease progression by influencing central nervous system (CNS)-immune pathways and neuroendocrine-immune networks. These interactions contribute to the pathogenesis of allergic, autoimmune, thyroid diseases, and malignancies. Mast cells and histamine are central to this process:

- Mast cells initiate early and late allergic responses, with histamine comprising 10% of their granules [22].
- Histamine induces bronchoconstriction, vasodilation, and inflammation, which can exacerbate conditions like systemic mastocytosis [21, 23].

Role of Mast Cells

Mast cells are activated in T-cell-mediated inflammatory responses. Mediators such as chemokines and neutrophils can trigger mast cell degranulation, resulting in bronchospasm and inflammation. Corticosteroids have been found to reduce the production and expression of transforming growth factor (TGF) and nitric oxide, highlighting their importance in airway remodeling [26].

Therapeutic Implications

- **Cromolyn Sodium**: This drug blocks respiratory neural reflexes and inhibits mast cell degranulation, effectively reducing TGF production and airway hyperresponsiveness.
- **Budesonide**: It reduces TGF expression, contributing to airway remodeling [26].
- **Bronchial Epithelium Changes**: Airway hyperresponsiveness involves increased sensory nerve activity, reduced inhibitory nerve responsiveness, and altered contractility factors, highlighting the importance of targeting these mechanisms in asthma therapy.

Role of Neuropeptides

Neuropeptides, including **substance P (SP)**, play a pivotal role in airway hyperresponsiveness [27]. Substance P acts on human skin, airways, nasal epithelium,

smooth muscle, and arterioles, causing vascular leakage, mucus secretion, bronchial constriction, mast cell degranulation, and various other effects [27]. Additionally, vasoactive intestinal peptide (VIP) can induce the release of substance P from nerve endings or directly elicit bronchial dilation by counteracting histamine effects on human airways [27]. Neuropeptides, such as substance P and VIP, also exhibit stimulatory and inhibitory effects on lymphocytes and macrophages.

Immune Receptors for Stress Hormones

Lymphocytes and monocytes express receptors for stress-related hormones, including corticotropin-releasing hormone (CRH), adrenocorticotropic hormone (ACTH), cortisol, norepinephrine, and epinephrine [28]. Sensory hyperresponsiveness has been demonstrated in the nasal mucosa, where neuropeptides potentiate inflammation. For instance, substance P significantly increases the production of interleukins (IL-1 to IL-6), tumor necrosis factor (TNF), and interferon (IFN) in allergic rhinitis mucosa [29].

Neuropeptide-Mediated Inflammation in Asthma

Endogenously produced substance P, released from vagal nerve fibers in the respiratory tract, alters airway microvascular permeability and smooth muscle tone, particularly in atopic and asthmatic patients experiencing bronchial hyperresponsiveness. Viral infections, irritants, and inflammation stimulate retrograde impulses, releasing substance P via axon reflexes. Neurogenic inflammation is upregulated by cytokines such as nerve growth factor (NGF) and interleukin-11, which are elevated in children with common colds and predispose them to asthma.

Stress and the Immune System

Cytokine Dysregulation

Stress affects cytokine balance, particularly interferon (IFN) and interleukin-10 (IL-10), resulting in a reduced IFN:IL-10 ratio during examination stress in children [30]. This shift toward a type 2 cytokine response under stress contributes to dysregulated immune activity, increasing susceptibility to viral infections, allergic reactions, and asthma exacerbations. Elevated IL-4, IL-5, and IL-13 levels in asthmatic children further compromise host defenses [28].

Th2 Hypothesis and Immunotherapy

Type 2 T-helper (Th2) cells play a critical role in initiating and maintaining allergic inflammation. Mast cells, which release IL-4, IL-10, and IL-13, signal memory T cells to differentiate into Th2 subsets. Immunotherapeutic approaches focus on modulating Th2 responses by:

- Inducing anergy in allergen-specific Th2 cells using allergen-derived peptides.
- Redirecting Th2 responses through allergen plus Th1-inducing cytokines.
- Targeting Th2 cell development or inhibiting Th2-related effector molecules with humanized antibodies or soluble receptors [31].

Cytokines, Chemokines, and Growth Factors

Th2-Driven Pathophysiology

Cytokines (IL-4, IL-5, IL-6, IL-9, IL-10, IL-13, granulocyte-macrophage colony-stimulating factor) and chemokines like eotaxin, transforming growth factor (TGF), and IL-11 contribute to allergic disorders. Peripheral cytokines can cross the blood-brain barrier or influence central nervous system cytokine production. These mediators alter neurotransmitter systems, particularly monoaminergic neurons, linking psychologic disturbances to physical symptoms.

Stress and Asthma

Psychologic Stress in Asthma

Asthmatic children experience heightened stress levels, which exacerbate asthma symptoms through:

- Elevated epinephrine and norepinephrine levels during acute stress, enhancing central nervous system arousal.
- Stress-induced alterations in immune and endocrine systems, increasing susceptibility to pathogens and autoimmune responses [33].

Impact of Stress on Viral Infections

Stress-related immune dysregulation affects the response to latent viruses such as herpes simplex virus-1 and Epstein-Barr virus. This is accompanied by reduced virus-

specific cytotoxic T-cell function, increasing infection susceptibility and asthma exacerbations.

Effects of Stress on Asthma and Quality of Life

HPA Axis Involvement

Cytokines, growth factors, and lipid mediators influence the hypothalamic-pituitary-adrenal (HPA) axis, contributing to stress-induced asthma. TNF is followed by IL-1 and IL-6 secretion, which stimulate both central and peripheral sympathetic systems. These inflammatory mediators affect airway function, exacerbate asthma symptoms, and contribute to comorbidities.

Asthma Exacerbations

Severe asthma exacerbations significantly impact quality of life (QoL), leading to:

- Increased hospital admissions.
- Decreased pulmonary function.
- Higher use of oral corticosteroids.

Approximately 40% of children with severe asthma require emergency visits annually, compared to 20% with moderate asthma and 15% with mild asthma [36]. Frequent exacerbations correlate with poorer QoL and higher healthcare burdens.

Emotional Stress as a Non-Allergic Trigger

Emotional stress is a critical non-allergic factor in asthma, influencing nitric oxide (NO) levels in exhalation and pulmonary function. Stress management through psychological counseling and educational programs improves outcomes in asthmatic children, emphasizing the importance of a multidisciplinary approach [36].

House Dust Mite Allergy and Its Strong Correlation with Asthma

House Dust Mite as a Key Etiology

A significant correlation exists between house dust mite allergy and asthma. A dose-response relationship has been reported between exposure to dust mite allergens and the sensitization and occurrence of symptomatic asthma, underscoring house dust

mites as a major cause of bronchial asthma [41]. Notably, gram-negative bacteria, which are integral components of house dust mites, play a crucial role in this relationship.

Role of Endotoxins in Asthma

Endotoxins, pro-inflammatory substances in the cell membranes of gram-negative bacteria, exacerbate airway responsiveness when inhaled. These endotoxins increase neutrophil counts in bronchoalveolar lavage fluid, contributing to airway inflammation [42]. The presence of endotoxin in house dust mites is hypothesized to significantly contribute to severe asthma, especially in children [43]. The severity of asthma correlates with endotoxin concentration in house dust mites, emphasizing its role in disease progression.

Assessment of Dust Mite Exposure

Skin Testing

Skin tests revealing wheals larger than 5 mm in diameter are indicative of strong positivity. Exposure to dust mite allergens is assessed using Group 1 allergens from *Dermatophagoides pteronyssinus*. This evaluation is further supported by measuring guanine concentration in house dust, which correlates with allergens such as Der p I and Der f I [44].

Dust Sampling

Dust collected from mattresses generally contains higher concentrations of Der p I and guanine than floor dust. Der p-specific IgE levels in the blood correlate more strongly with Der p I concentrations in mattress dust than in floor dust. Individuals with Der p I levels exceeding 10 µg/g of dust or guanine levels greater than 0.10 mg/100 mg of dust are at greater risk of developing asthma compared to rhinitis [40].

Endotoxin Concentrations in Dust

Endotoxin levels in house dust mites, approximately 2 ng/mg of dust, are comparable to occupational exposures linked to bronchial diseases. These levels are higher in certain occupational environments, such as cotton (0.04–39.1 ng/mg) and grain dust (1.6–24.6 ng/mg), and lower in swine (50–360 ng/mg) and poultry dust (13.0–4.7

ng/mg). Gram-negative bacteria like *Enterobacter agglomerans* and *Pseudomonas syringae* are commonly found in occupational dust, contributing to the endotoxin load [40].

Environmental and Occupational Factors

Bacterial Contamination

Household dust often harbors gram-negative bacteria such as *Escherichia vulneris* and *Pseudomonas fluorescens*. Higher endotoxin concentrations in house dust are associated with a greater likelihood of developing asthma in children. This highlights the role of dust mite allergens and endotoxins as critical environmental triggers that increase asthma severity by exacerbating airway inflammation [40].

Neutrophil Response

Inhaled endotoxin-contaminated allergens alter cellular responses in bronchoalveolar lavage fluid, characterized by increased neutrophil activity rather than eosinophil presence. This neutrophilic inflammation is a hallmark of severe asthma [40].

Animal Contact, Microbial Exposures, and Asthma Prevalence

Lower Asthma Prevalence in Rural Areas

Children in rural areas often experience lower rates of asthma compared to urban counterparts. This difference is attributed to lifestyle factors such as close animal contact and microbial exposures. In India, rural children exhibit lower prevalence rates of asthma, wheezing, rhinitis, and atopic sensitization compared to urban children [46, 47].

Protective Role of Microbial Exposures

Exposure to microbes, such as those associated with gastrointestinal infections or parasitic infestations, is linked to lower rates of atopy in rural populations. Children raised in farming communities, with frequent exposure to endotoxin and other microbial components, exhibit reduced prevalence of asthma and allergic conditions.

Breastfeeding and Microbial Benefits

Approximately 74% of rural Indian children are exclusively breastfed for over six months, compared to 20% of urban children. Breastfeeding is associated with lower

asthma and atopy rates, possibly due to immune protection mediated by breast milk components such as transforming growth factor (TGF) and soluble CD14. Additionally, traditional Indian diets, including fermented foods rich in *Lactobacillus*, may enhance the quality of breast milk and contribute to protective effects against asthma and atopy [47, 49].

Environmental Factors and Housing Conditions

Rural Housing and Microbial Load

Rural homes with mud floors, cow dung usage, and indoor animal housing have higher microbial DNA loads and endotoxin concentrations. These exposures promote regulatory immune responses, such as increased interleukin-10 levels, reducing the risk of asthma and atopy. In contrast, urban homes with brick and cement construction lack these beneficial microbial exposures [47].

Impact of Environmental Pollutants

Urban areas exhibit higher levels of passive tobacco smoke, automobile pollution, and indoor pollution from cooking fuels. These factors increase asthma prevalence and severity, contrasting with the protective environmental conditions in rural settings.

Classifying Asthma Severity in Children

Guidelines for Classification

The **National Asthma Education and Prevention Program (NAEPP)** has established guidelines for the classification of asthma severity. These classifications are essential for consistent, objective assessment and for determining appropriate therapy. Asthma is categorized into four levels of severity based on symptom frequency, pulmonary function tests, and medication usage:

1. **Mild Intermittent Asthma**
2. **Mild Persistent Asthma**
3. **Moderate Persistent Asthma**
4. **Severe Persistent Asthma** [20].

Pulmonary Function Metrics

Forced Expiratory Volume (FEV1) Percent Predicted

FEV1 percentage predicted is a core criterion for determining asthma severity:

- **Above 80% predicted**: Mild asthma (intermittent or persistent).
- **60–80% predicted**: Moderate asthma.
- **Below 60% predicted**: Severe asthma [20].

These classifications, derived from expert opinion, have not been validated through prospective or retrospective studies in children or adults. Interestingly, children aged 5–12 years with mild to moderate persistent asthma had a mean FEV1 of 93% predicted, indicating potentially higher lung function than suggested by these classifications. Differences in lung growth effects between boys and girls may necessitate separate standards. Moreover, the guidelines do not provide specific criteria for other pulmonary function measures like the FEV1/FVC ratio, which is increasingly abnormal in severe asthma [20].

NAEPP/EPR2 Criteria for Symptom-Based Classification

Symptom Frequency

The NAEPP/EPR2 guidelines classify asthma severity based on daytime, nighttime, and exertional symptoms:

- **Mild Intermittent**: Symptoms ≤2 days per week, ≤2 nights per month, or ≤2 exertional episodes per month.
- **Mild Persistent**: Symptoms 3–6 days per week, 3–4 nights per month, or 3–4 exertional episodes per month.
- **Moderate Persistent**: Daily symptoms, 5–9 nights per month, or 5–9 exertional episodes per month.
- **Severe Persistent**: Continuous symptoms, >10 nights per month, or >10 exertional episodes per month [14].

Medication-Based Classification

Asthma severity is also categorized by the type and dosage of medications required for control, as outlined in the NAEPP/EPR2 guidelines:

- **Mild Persistent**: Use of low-dose inhaled corticosteroids (ICS) or another controller medication (e.g., leukotriene receptor antagonists, cromolyn, nedocromil, or theophylline) alone for at least 5 days per week.
- **Moderate Persistent**: Use of low-dose ICS with one additional controller medication or medium-dose ICS alone.
- **Severe Persistent**: Use of moderate-dose ICS with additional controller medication, high-dose ICS, or more than two controller medications [9].

Table: Asthma Severity Classification

Severity Level	**Symptom Frequency**	**Pulmonary Function (FEV1 % Predicted)**	**Medication Use**
Mild Intermittent	- ≤2 days/week (daytime symptoms) - ≤2 nights/month (nighttime symptoms) - ≤2 exertional episodes/month	>80% predicted	No daily medication required.
Mild Persistent	- 3–6 days/week (daytime symptoms) - 3–4 nights/month (nighttime symptoms) - 3–4 exertional episodes/month	>80% predicted	- Low-dose ICS or - Another controller medication (e.g., leukotriene receptor antagonist, cromolyn, nedocromil, or theophylline).
Moderate Persistent	- Daily symptoms - 5–9 nights/month (nighttime	60–80% predicted	- Low-dose ICS + one additional controller medication

	symptoms) - 5–9 exertional episodes/month		OR - Medium-dose ICS alone.
Severe Persistent	- Continuous symptoms - >10 nights/month (nighttime symptoms) - >10 exertional episodes/month	<60% predicted	- Moderate-dose ICS + additional controller medication OR - High-dose ICS OR - More than two controller medications.

Bronchial Asthma Management

Asthma management relies on evidence-based guidelines to provide effective diagnosis, treatment, and follow-up care. The **Global Initiative for Asthma (GINA)** and the **British Thoracic Society** guidelines serve as the cornerstone of asthma management, ensuring transparency and efficacy in therapy.

Goals of Asthma Management (GINA 2022) [1]

1. **Symptom Control**: Achieve and maintain normal activity levels while minimizing exacerbations and adverse effects of therapy.
2. **Patient-Centered Approach**: Incorporate the views and goals of asthmatic children and their families into treatment plans.
3. **Effective Communication**: Establish strong communication to enhance therapy adherence and outcomes.

Asthma Management Protocols

Initial Controller Treatment for Children (6–11 Years) [1]

- **Early Initiation**: Start controller therapy immediately upon asthma diagnosis for optimal outcomes.
- **Indications for Low-Dose Inhaled Corticosteroids (ICS)**:

- Symptoms >2 times per month.
- Nocturnal awakenings >1 time per month.
- Additional risk factors for exacerbation.

- **Severe Uncontrolled Symptoms**: Consider higher steps of therapy, such as medium/high-dose ICS or ICS with long-acting beta-agonist (LABA).

Stepwise Dosing for Adolescents (≥12 Years) [1]

Medication	**Low Dose (µg)**	**Medium Dose (µg)**	**High Dose (µg)**
Beclometasone Dipropionate	200–500	500–1000	>1000
Budesonide	200–400	400–800	>800
Ciclesonide	80–160	160–320	>320
Fluticasone Propionate	100–250	250–500	>500
Mometasone Furoate	110–220	220–440	>440
Triamcinolone Acetonide	400–1000	1000–2000	>2000

Dosing for Children (6–11 Years) [1]

Medication	**Low Dose (µg)**	**Medium Dose (µg)**	**High Dose (µg)**
Beclometasone Dipropionate	100–200	200–400	>400
Budesonide (DPI)	100–200	200–400	>400
Budesonide (Nebules)	250–500	500–1000	>1000
Ciclesonide	80	80–160	>160
Fluticasone Propionate (DPI)	100–200	200–400	>400
Fluticasone Propionate (HFA)	100–200	200–500	>500
Mometasone Furoate	110	220–440	>440
Triamcinolone Acetonide	400–800	800–1200	>1200

Management for Children ≤5 Years [1]

- **Initial Therapy**: A low-dose ICS combined with a short-acting beta-agonist (SABA) for symptom control.
- **Dosing for Low-Dose ICS**:
    - Beclometasone Dipropionate: 100 µg.
    - Budesonide (MDI): 200 µg; Nebulizer: 500 µg.
    - Fluticasone Propionate (HFA): 100 µg.
    - Ciclesonide: 160 µg.
    - **Note**: Mometasone Furoate and Triamcinolone Acetonide lack evidence in children under five years.

Management of Asthma Exacerbations

Primary Management for Children ≤5 Years

1. **Oxygen Support**: Maintain SpO_2 >94% via face mask.
2. **SABA Administration**: Salbutamol (2.5 mg via nebulizer or 2–6 puffs via spacer) every 20 minutes for the first hour.
3. **Systemic Corticosteroids**:
    - Prednisolone: 1–2 mg/kg (up to 20 mg for <2 years; up to 30 mg for 2–5 years).
4. **Additional Options**:
    - Ipratropium Bromide: 80 µg/puff, 2 puffs every 20 minutes for 1 hour.
    - Nebulized Magnesium Sulfate: 150 mg (≥2 years) up to three doses.

Primary Prevention Guidelines [1]

1. Avoid smoking during pregnancy and early childhood.
2. Promote normal vaginal delivery.
3. Encourage breastfeeding.
4. Limit use of paracetamol and antibiotics during the first year of life.

Global Actions to Reduce Asthma Burden [2]

1. Recognize asthma as a significant global health issue.
2. Monitor asthma prevalence and adverse outcomes worldwide.
3. Address economic and political barriers to asthma care.
4. Improve access to essential medications in low-income countries.
5. Identify and mitigate indoor and outdoor pollution contributing to asthma.
6. Promote anti-tobacco measures and reduce tobacco consumption.
7. Develop realistic asthma guidelines for developing countries.
8. Integrate GINA guidelines with other global policies for unified management.
9. Encourage cost-effective treatment strategies to reduce mortality and morbidity.

Educational Intervention on the Use of Metered Dose Inhaler:

Asthma is a chronic respiratory condition that requires effective management to control symptoms, prevent exacerbations, and improve the quality of life. Inhalation therapy, specifically using metered dose inhalers (MDIs), is central to asthma management in children aged 6–18 years. However, improper MDI use remains a significant barrier to achieving optimal therapeutic outcomes. Educational interventions targeting children and their caregivers have shown promise in addressing this issue, and the Al-Worafi criteria provide a structured approach to evaluating such interventions. This paper explores the impact of educational interventions on MDI usage in asthmatic children, emphasizing the application of the Al-Worafi criteria.

The Al-Worafi Criteria

The Al-Worafi criteria, proposed by Yemeni pharmacist Mohammed Al-Worafi, provide a comprehensive framework for evaluating the effectiveness of educational interventions in improving inhaler technique and adherence. These criteria focus on several key aspects:

1. **Knowledge Enhancement**: Increasing awareness of asthma, its management, and the importance of proper MDI technique.

2. **Skill Improvement**: Ensuring that children can demonstrate correct MDI use.
3. **Behavioral Change**: Promoting adherence to prescribed regimens through regular follow-ups and motivation.
4. **Outcome Monitoring**: Assessing the clinical outcomes, including symptom control and reduction in exacerbations.

By addressing these elements, the criteria aim to ensure that educational interventions produce measurable improvements in asthma management.

Barriers to Effective MDI Use in Children

Asthmatic children face several challenges in using MDIs correctly, including:

1. **Poor Technique**: Studies consistently show that a large percentage of children misuse MDIs, often failing to coordinate inhalation with actuation.
2. **Lack of Awareness**: Many children and caregivers are unaware of the importance of correct inhaler technique and adherence.
3. **Limited Access to Education**: In resource-limited settings, healthcare providers may not have the time or resources to provide detailed instructions on MDI use.
4. **Psychological Factors**: Fear of social stigma, anxiety, and lack of motivation can affect adherence.
5. **Parental Role**: Caregivers' limited knowledge or incorrect assumptions about asthma management can hinder effective MDI use.

Educational Interventions and Their Role

Educational interventions aim to bridge the gap between prescription and proper use of MDIs. Such interventions can be delivered in various forms, including one-on-one training, group sessions, multimedia tools, and community-based programs. These programs focus on:

1. **Demonstrating Proper Technique**: Visual and hands-on demonstrations help children learn the correct steps for MDI use.
2. **Reinforcing Learning**: Repeated instructions and follow-ups ensure retention of knowledge and skills.

3. **Motivational Strategies**: Encouraging adherence through positive reinforcement and goal setting.
4. **Parental Involvement**: Educating caregivers to support their children's asthma management.

Implementation of Al-Worafi Criteria in Educational Interventions

1. Knowledge Enhancement

Educational programs based on the Al-Worafi criteria emphasize improving the understanding of asthma and the role of MDIs. Key topics include:

- Pathophysiology of asthma and the importance of controlling inflammation.
- Benefits of inhalation therapy over systemic treatments.
- Risks associated with improper MDI use, such as inadequate symptom control and increased exacerbations.

By increasing awareness, children and caregivers become more engaged in asthma management.

2. Skill Improvement

Proper technique is critical for the effective delivery of medication. Al-Worafi criteria recommend step-by-step training, including:

- Shaking the inhaler before use.
- Exhaling fully before placing the mouthpiece.
- Coordinating actuation with a slow, deep inhalation.
- Holding the breath for 5–10 seconds after inhalation.
- Cleaning the inhaler regularly to maintain its functionality.

Demonstrations, video tutorials, and supervised practice sessions can help children master these steps.

3. Behavioral Change

Changing behaviors involves addressing psychological and social factors that influence adherence. Educational programs should:

- Provide emotional support to reduce anxiety related to inhaler use.

- Encourage children to view MDI use as a normal part of their daily routine.
- Highlight the benefits of adherence, such as fewer symptoms and better participation in activities.
- Engage caregivers in monitoring and motivating adherence.

4. Outcome Monitoring

Monitoring clinical outcomes is essential to assess the effectiveness of educational interventions. Key measures include:

- Reduction in asthma symptoms (e.g., coughing, wheezing, breathlessness).
- Fewer nocturnal awakenings due to asthma.
- Decreased need for rescue medications.
- Improved lung function, as measured by peak expiratory flow rate (PEFR) or spirometry.
- Reduced frequency of emergency visits and hospitalizations.

Regular follow-ups and feedback sessions ensure that any gaps in understanding or technique are promptly addressed.

Evidence Supporting Educational Interventions

Several studies have demonstrated the positive impact of educational programs on MDI use in asthmatic children. For instance:

1. **Individualized Training**: Studies show that one-on-one training sessions significantly improve MDI technique and adherence.
2. **School-Based Programs**: Programs conducted in schools have successfully educated large groups of children about asthma management, leading to better symptom control.
3. **Multimedia Tools**: Video demonstrations and interactive apps have proven effective in reinforcing proper inhaler use.
4. **Parental Education**: Training caregivers has been associated with better asthma outcomes in children, as parents play a crucial role in ensuring adherence.

Challenges in Implementing Educational Interventions

Despite their benefits, educational programs face several challenges:

1. **Resource Constraints**: In low-income settings, limited access to healthcare professionals and educational materials can hinder program implementation.
2. **Language and Cultural Barriers**: Programs must be tailored to the linguistic and cultural needs of diverse populations.
3. **Sustainability**: Ensuring long-term adherence requires ongoing education and support, which may strain resources.
4. **Variability in Outcomes**: The effectiveness of interventions may vary depending on factors such as the child's age, socioeconomic status, and family dynamics.

RECENT STUDIES:

Roopavathy GM et al. (2023) conducted a study to assess the effect of an educational program on asthma knowledge and proper metered-dose inhaler (MDI) usage among asthma patients. The research was carried out on inpatients admitted to the Department of Pulmonary Medicine at Victoria Hospital, BMCRI. A pre- and post-intervention design was used, incorporating a questionnaire to evaluate asthma knowledge and a demonstration of MDI technique based on a standard checklist. The findings revealed a significant increase in asthma knowledge, with the mean percentage score rising from 45.45% before the intervention to 88.63% afterward (**$P < 0.0001$**). Similarly, the demonstration of correct pMDI usage improved markedly, increasing from 25% pre-intervention to 62% post-intervention (**$P < 0.0001$**).

Abegaz TM et al. (2020) conducted a study to explore barriers to proper MDI use, assess competency levels, and examine the impact of these factors on asthma control among adult patients. This prospective cross-sectional study took place at the outpatient department of the University of Gondar Comprehensive Specialized Hospital. A total of 307 participants were interviewed using structured questions to assess their inhaler competency, asthma control, and barriers to effective MDI use.

The study population consisted of 170 females (55.4%), with the majority residing in urban areas (185 participants, 60.3%). The mean age of respondents was 51.77 years (±15.40). The most frequently identified barriers included the cost of medication (91.9%) and the belief that medication should only be used in response to symptoms (90.2%). Only 56 participants (18.2%) demonstrated competency in MDI usage, and a mere 17 patients (5.5%) achieved well-controlled asthma. Incompetence in MDI use was found to be a significant factor reducing asthma control, with an adjusted odds ratio (AOR) of 0.168 [95% CI: 0.41–0.687].

Carvalho Coelho AC et al. (2016) conducted a comprehensive literature review to evaluate the impact of educational interventions on asthma knowledge and morbidity among children and adolescents. The review included 17 studies involving 5,879 participants, most of whom were from developed countries. These interventions were primarily led by health professionals and targeted children diagnosed with asthma. The findings revealed that asthma education significantly improved knowledge about the disease in at least one area assessed in the studies. Additionally, the interventions resulted in a 29% reduction in asthma symptoms, a 35% decrease in hospitalizations and emergency visits, a 29% reduction in school absenteeism, and a 41% improvement in the quality of life. This review emphasized the importance of school-based educational programs in managing asthma effectively and reducing its overall burden among children and adolescents.

Nalini GK et al. (2016) conducted an interventional study to assess the effectiveness of various educational methods in improving the correct usage of pressurized metered-dose inhalers (pMDIs) among 60 second-year medical students in the Department of Pharmacology at HIMS, Hassan. The participants were divided into three groups and received educational interventions through video clips, information leaflets, and physical demonstrations by trained faculty. The evaluation was conducted pre-intervention, one week post-intervention, and one month post-intervention using the National Asthma Education and Prevention Program (NAEPP) criteria. At baseline, the mean scores for written knowledge and skill demonstration were 2.13 ± 1.49 and 3.78 ± 1.06, respectively. After the intervention, these scores increased significantly to 7.15 ± 1.41 and 7.37 ± 1.67 ($p < 0.05$). Among the methods,

physical demonstration showed the highest improvement, with scores significantly higher than the video and leaflet groups at one week (8.8 vs. 7.2 and 6.1, respectively; $p < 0.05$) and one month (8.25 vs. 7.1 and 5.7, respectively; $p < 0.05$). This study concluded that hands-on demonstrations are the most effective educational method for improving pMDI knowledge and technique.

Jolly GP et al. (2015) evaluated the effectiveness of educational interventions in improving MDI usage techniques among 117 participants. The study initially assessed inhaler technique using a standard checklist based on National Institute of Health (NIH) guidelines. At baseline, only one participant could perform all steps of MDI usage correctly, and the overall median score for the group was 3 (range: 1–8). The participants were then divided into two groups for educational training: one group received written step-by-step instructions, while the other underwent physical demonstrations using a placebo device. Post-intervention, the median scores increased to 6, 7, and 8 after the first, second, and third sessions, respectively. At one-month follow-up, the median score slightly dropped to 7 but improved again with additional training sessions. The study found that participants in the physical demonstration group showed significantly greater improvement in median scores compared to the written instruction group (3.0 vs. 2.0; $p < 0.001$). The findings highlight the effectiveness of physical demonstrations in enhancing MDI technique and sustaining long-term competency.

MATERIALS AND METHODS

MATERIAL AND METHODS

Study design: Prospective Analytical study

Study Place: Paediatrics OPD and In Patient Department, Santosh Medical College and Hospital, Ghaziabad

Minimum Sample Size Required: 112 children on MDI Treatment (with 95% confidence interval and 5% margin of error)

Sampling Frame: Asthma patients visiting Pediatric Chest Clinic, Pediatric OPD and admitted in ward on MDI treatment in Santosh Hospital, Ghaziabad

Used Formula: $n = [DEFF*Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1)+p*(1-p)]$

Ethical Clearance: Ethical clearance was taken from the ethical committee at Santosh Medical College and Hospital, Ghaziabad.

Inclusion Criteria:

- Patients with Asthma between 6-18 years of age on MDI treatment

Exclusion Criteria:

- Children whose parents did not give consent.
- Patients on oral medication for Asthma
- Patients with nasal and oral anatomical abnormalities
- Patients with other chronic respiratory diseases

METHOD OF DATA COLLECTION

 The intervention consisted of showing videos demonstrating all 9 steps of MDI use and handing over a brochure illustrating these steps.

 Data were collected in two phases: baseline and post-intervention, with a gap of four weeks in between.

 Inhaler technique was assessed by the primary investigator.

 Correct technique, based on the Al-Worafi criteria, was demonstrated using a placebo MDI.

 Any skipped or incorrect step was explained again.

 A hard copy of the checklist was handed over to the subjects or their parents.

 An asthma symptom control diary was also provided to the family.

 The participants were contacted weekly or as needed, with instructions to demonstrate MDI use at each visit and to bring the symptom control diary.

Table 1: Recommended Checklist of Metered-Dose Inhaler (MDI).[3,4,8]

	Step	Score
1	**Shake the inhaler well.**[a]	
2	**Remove the dust cap.**[a]	
3	Exhale slowly through pursed lips.	
4	If using the "closed-mouth" technique, hold the inhaler upright and place the mouthpiece between your lips. Be careful not to block the opening with your tongue or teeth. If using the "open-mouth" technique, open your mouth wide and hold the inhaler upright 1–2 inches from your mouth, making sure the inhaler is properly aimed.	
5	**Press down on the inhaler once as you start a slow, deep inhalation.**[a]	
6	Continue to inhale slowly and deeply through your mouth. Try to inhale for at least 5 s.	
7	Hold your breath for 10 s (use your fingers to count to 10 slowly). If 10 s makes you feel uncomfortable, try to hold your breath for at least 4 s.	
8	Exhale slowly.	
9	Wait at least 30–60 s before inhaling the next puff of medicine.	

[a] Critical steps.

Out of total 9 steps, each step was scored 1.

Incorrect, skipped and correct steps were noted.

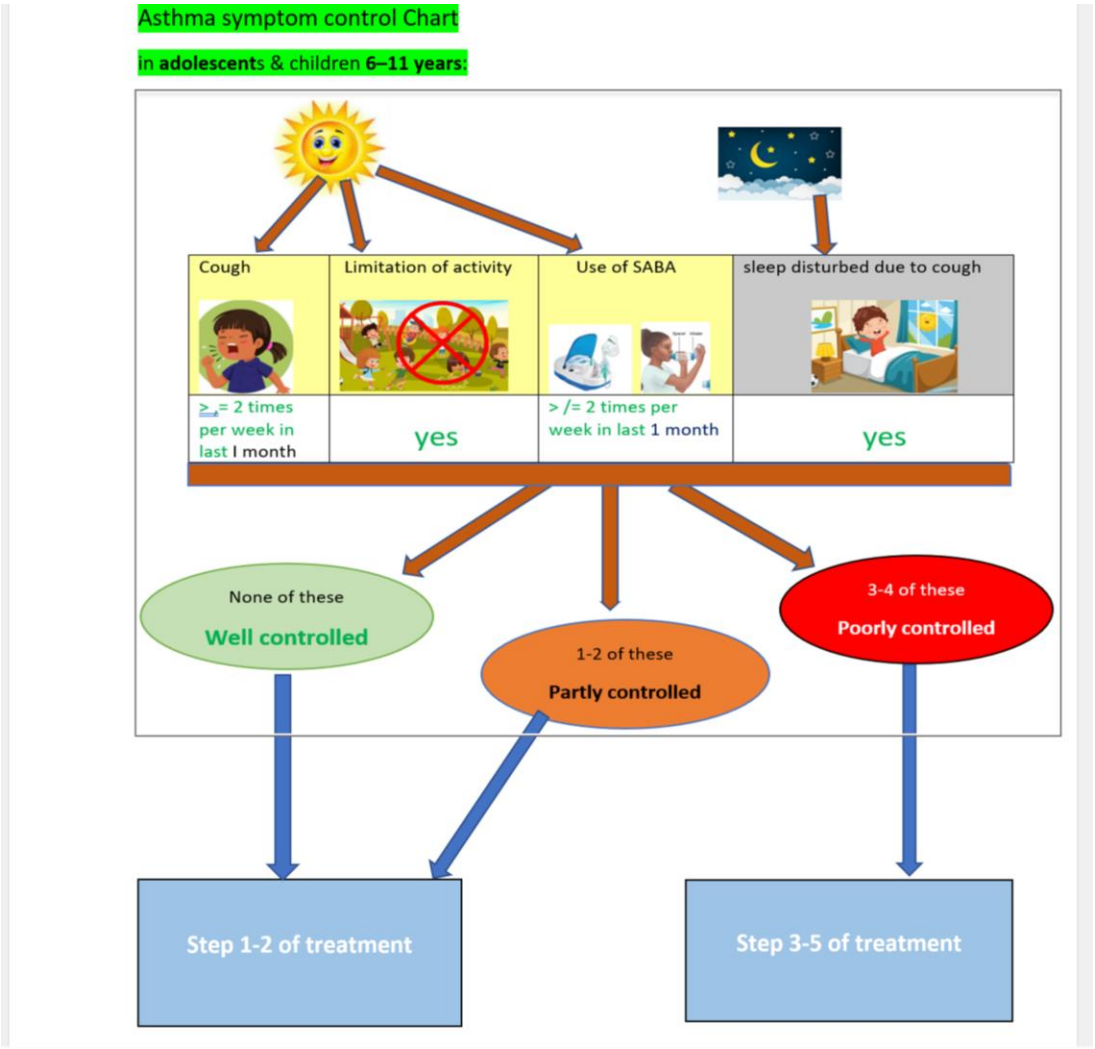
Incorrect and skipped steps were marked as zero.

Sum of combined score was recorded out of 9.

Good Technique: ≥ 7–9

Moderate technique: 5 or 6

Poor technique: ≤ 4



STATISTICAL ANALYSIS:

The questionnaires were initially checked for completeness, and data was cleaned for errors and missing values. The corrected data was then entered into Microsoft Excel after preparing a Master-chart. Data analysis was done using licensed SPSS software version 21.0 (Chicago, Illinois). Univariate analyses was done initially and the results were presented with the help of tables, text, bar-diagrams and pie-charts. Descriptive statistics were used to calculate frequencies of categorical variables, and measures of central tendencies and dispersion were used to describe continuous variables. Chi square test was used to compare the CRS with others and A p value <0.05 was considered significant.

OBSERVATIONS & RESULTS

OBSERVATIONS AND RESULTS

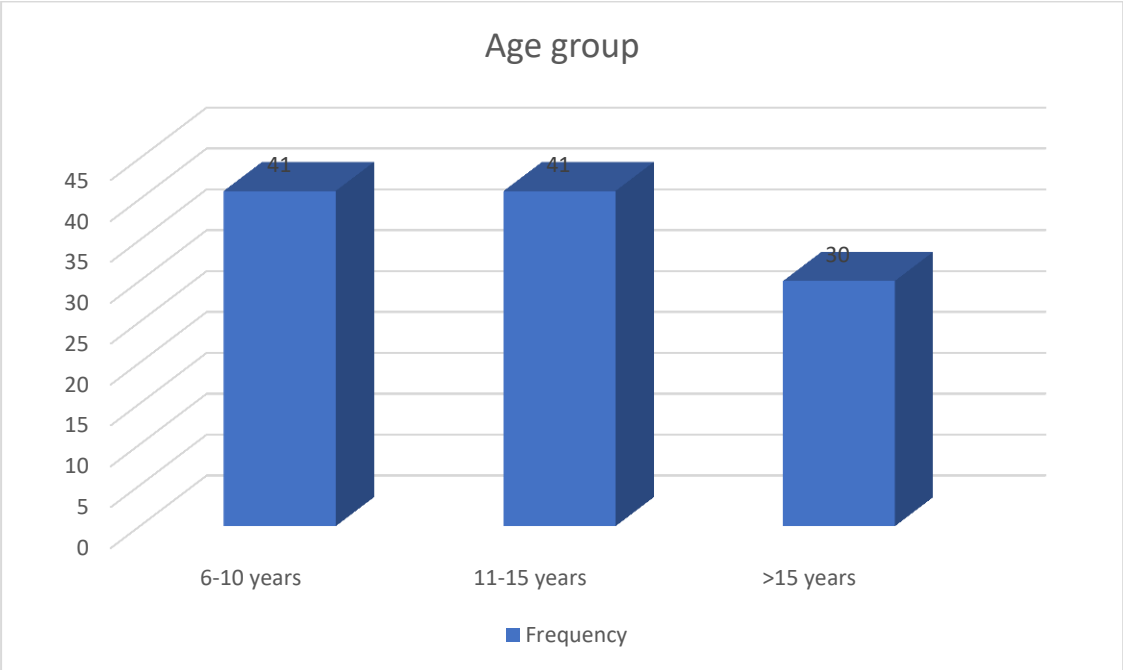
Table 1: Age (years) distribution of study participants:

Mean	11.973
Median	12.000
Std. Deviation	3.9053
Minimum	6.0
Maximum	18.0

The mean age of the 112 study participants was 11.97 years with a standard deviation of 3.91 years. The minimum and maximum ages recorded were 6 and 18 years, respectively.

Table 2: Distribution of study participants according to age group

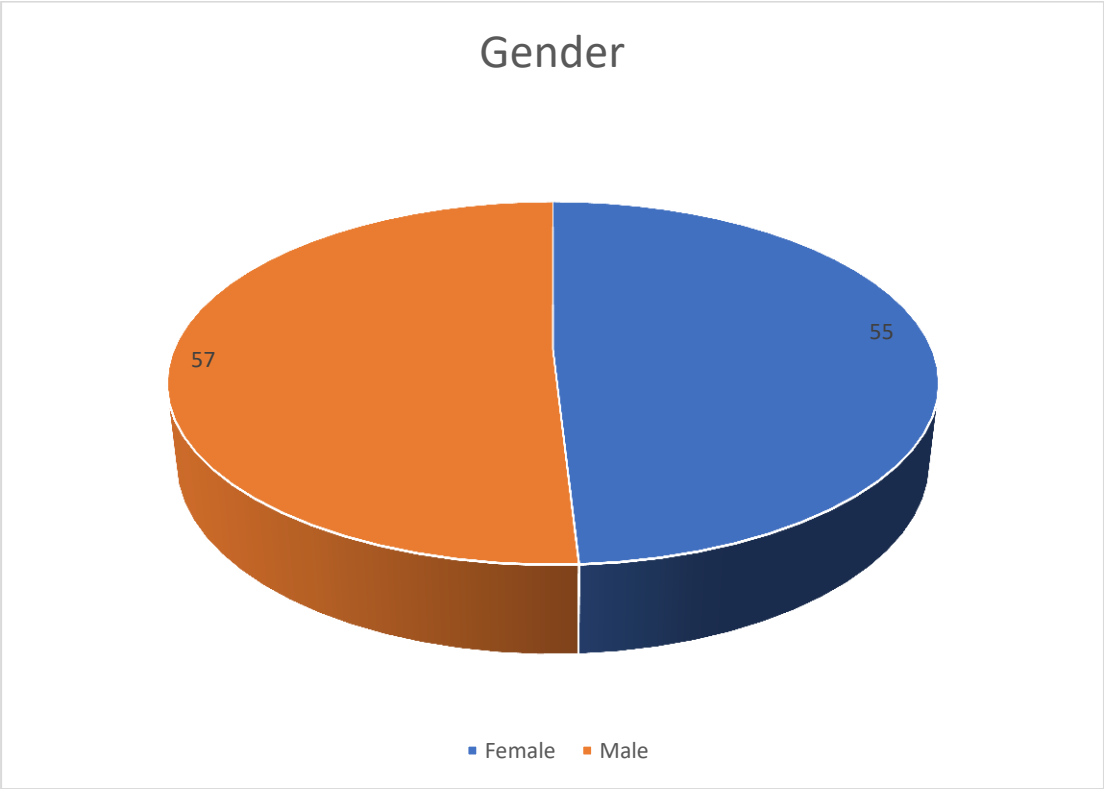
Age group	Frequency	Percent
6-10 years	41	36.6
11-15 years	41	36.6
>15 years	30	26.8
Total	112	100.0



When categorized into age groups, 41 participants (36.6%) were between 6–10 years, another 41 participants (36.6%) were aged between 11–15 years, and 30 participants (26.8%) were older than 15 years.

Table 3: Distribution of study participants according to gender

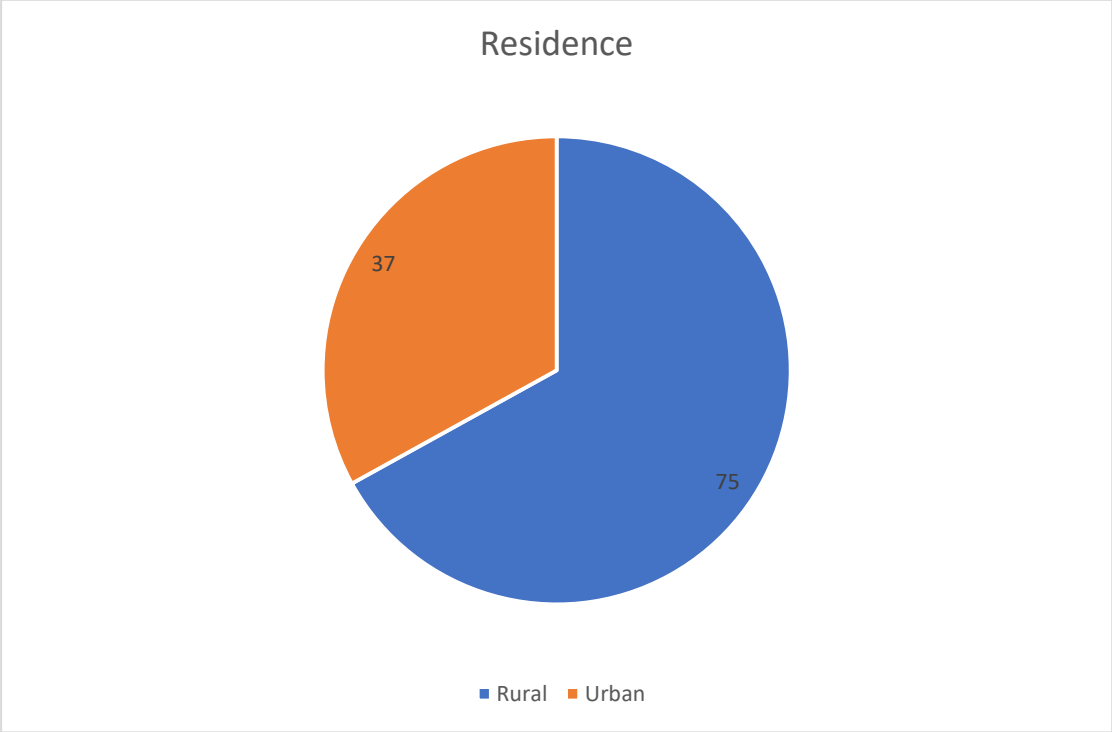
Gender	Frequency	Percent
Female	55	49.1
Male	57	50.9
Total	112	100.0



Among the total participants, 57 (50.9%) were male and 55 (49.1%) were female, indicating a nearly equal gender distribution with a slight male predominance.

Table 4: Distribution of study participants according to residence

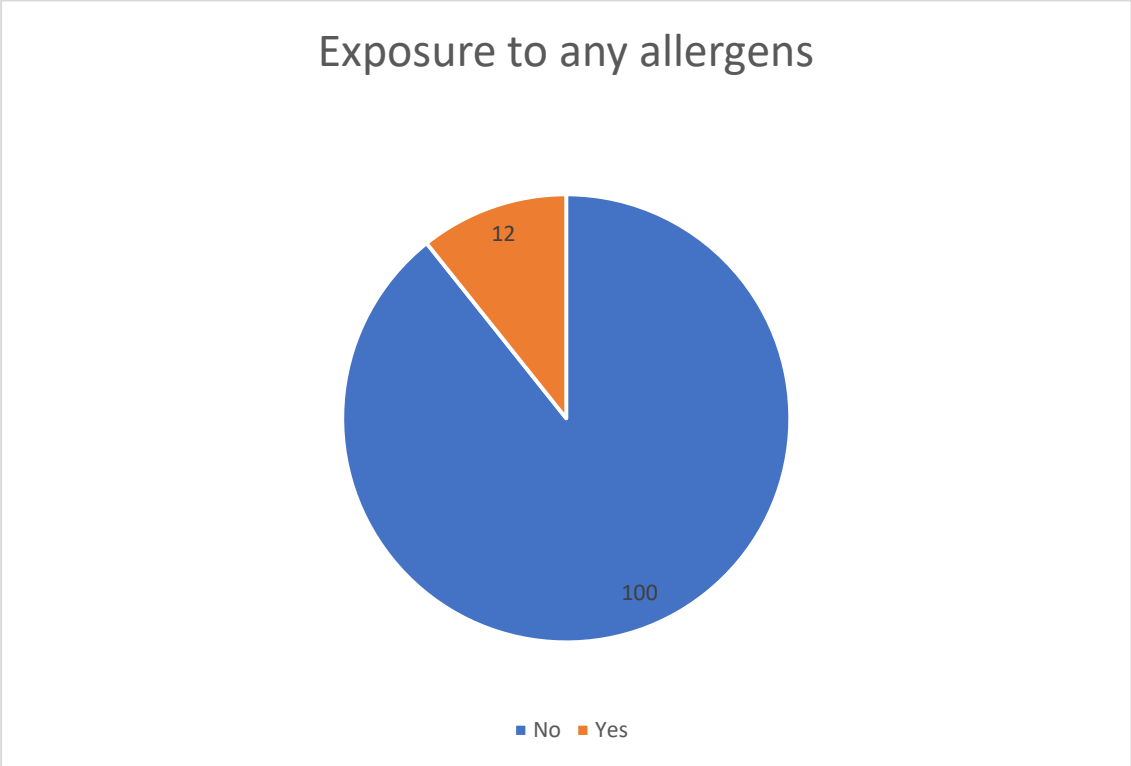
Residence	Frequency	Percent
Rural	75	67.0
Urban	37	33.0
Total	112	100.0



A majority of the study population resided in rural areas, comprising 75 participants (67.0%), while 37 participants (33.0%) were from urban settings.

Table 5: Distribution of study participants according to exposure to any allergens

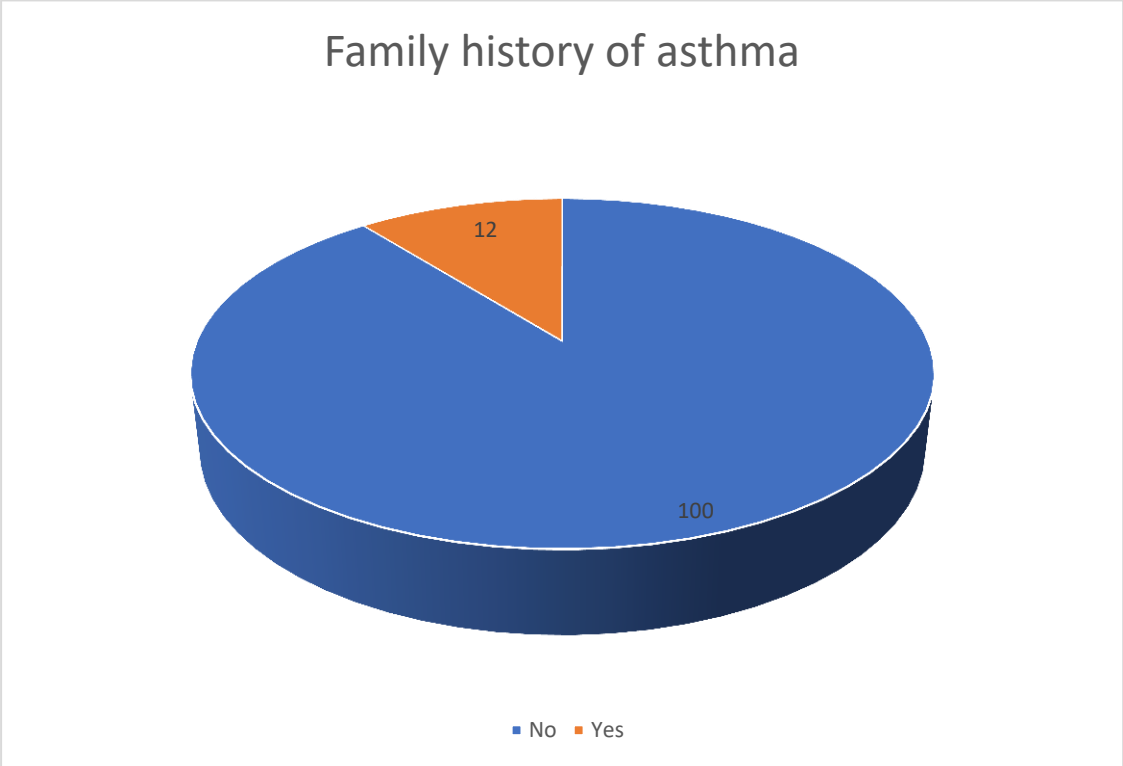
Exposure to allergens	Frequency	Percent
No	100	89.3
Yes	12	10.7
Total	112	100.0



Exposure to allergens was reported by 12 participants (10.7%), whereas the remaining 100 participants (89.3%) had no known exposure to any allergens.

Table 6: Distribution of study participants according to family history if asthma

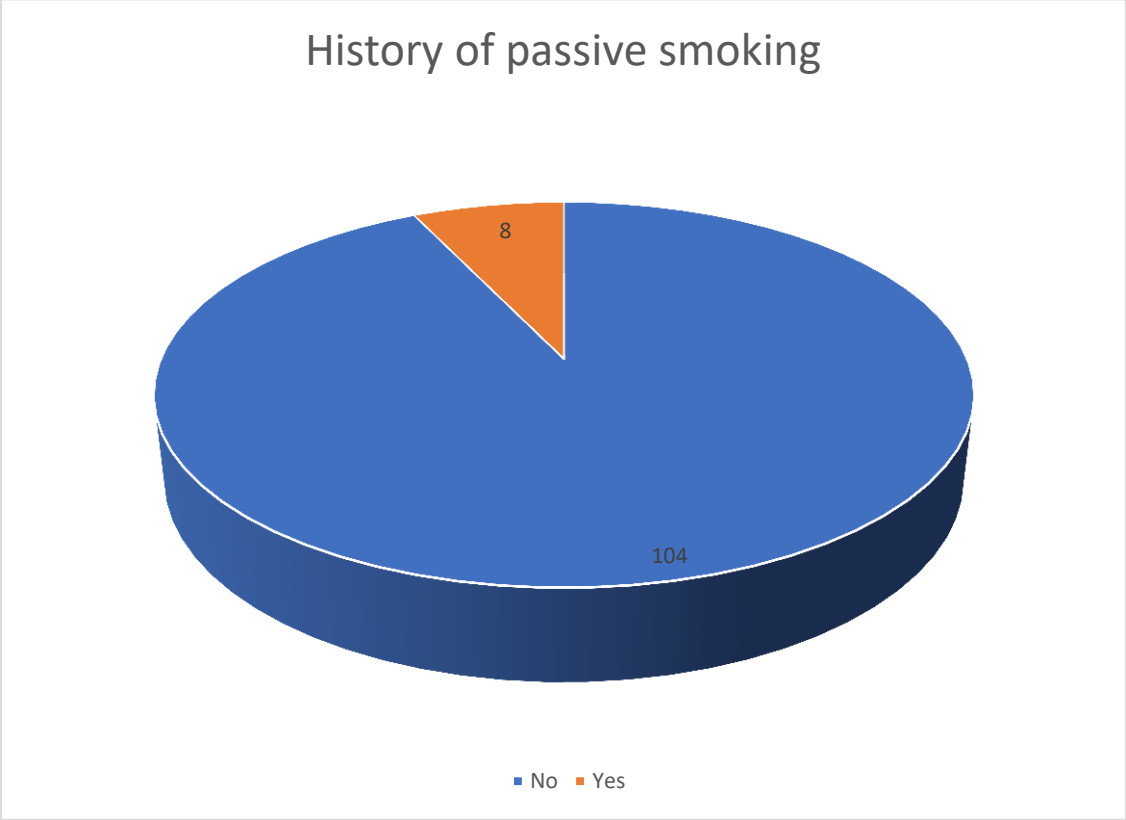
Family history of asthma	Frequency	Percent
No	100	89.3
Yes	12	10.7
Total	112	100.0



A positive family history of asthma was present in 12 participants (10.7%). The remaining 100 participants (89.3%) did not report any family history of asthma.

Table 7: Distribution of study participants according to history of passive smoking

History of passive smoking	Frequency	Percent
No	104	92.9
Yes	8	7.1
Total	112	100.0

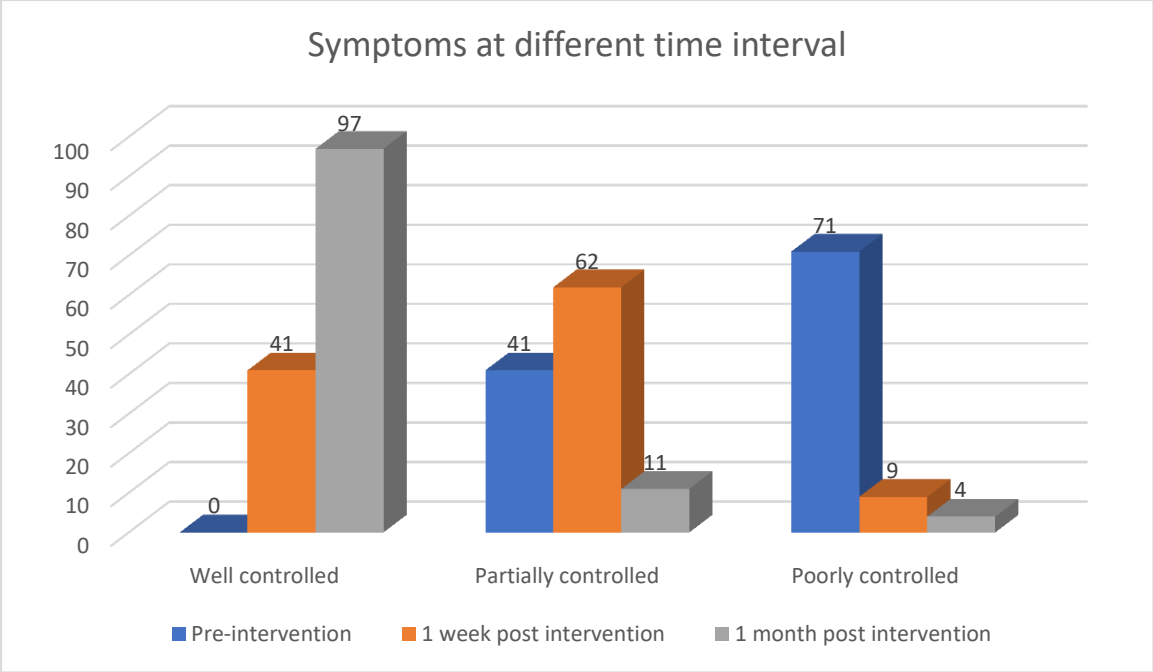


History of passive smoking was documented in 8 participants (7.1%), while 104 participants (92.9%) had no history of exposure to passive smoking.

Table:8 Comparison of symptoms at different time interval

Symptoms	Pre-intervention		1 week post intervention		1 month post intervention	
	n	%	n	%	n	%
Well controlled	0	0	41	36.6	97	86.6
Partially controlled	41	36.6	62	55.4	11	9.8
Poorly controlled	71	63.4	9	8.0	4	3.6
p-value	0.0001					
p-value (compare to pre-intervention			0.0001		0.0001	

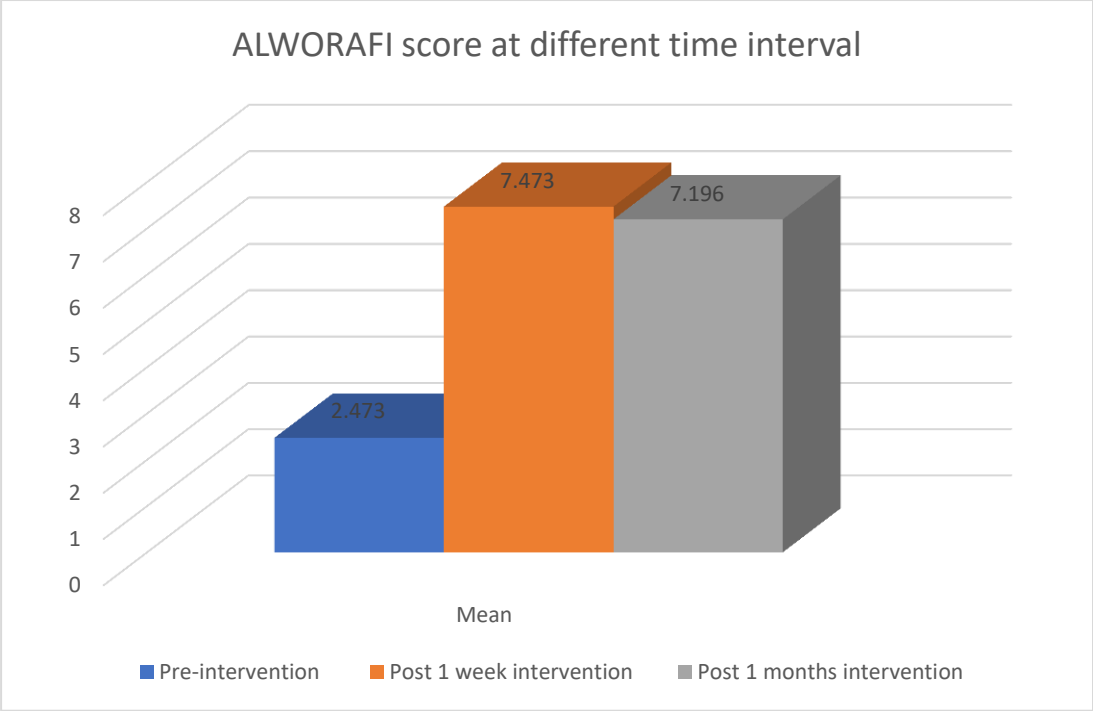
*Chi Square test



Symptom control status showed significant improvement following intervention. Pre-intervention, 71 participants (63.4%) had poorly controlled symptoms, while 41 (36.6%) were partially controlled, and none were well controlled. At 1 week post-intervention, 41 participants (36.6%) had well-controlled symptoms, 62 (55.4%) were partially controlled, and only 9 (8.0%) remained poorly controlled. After 1 month, 97 participants (86.6%) were well controlled, 11 (9.8%) were partially controlled, and only 4 (3.6%) had poorly controlled symptoms. The improvement over time was statistically significant (p=0.0001).

Table 9: Comparison of ALWORAFI score at different time interval:

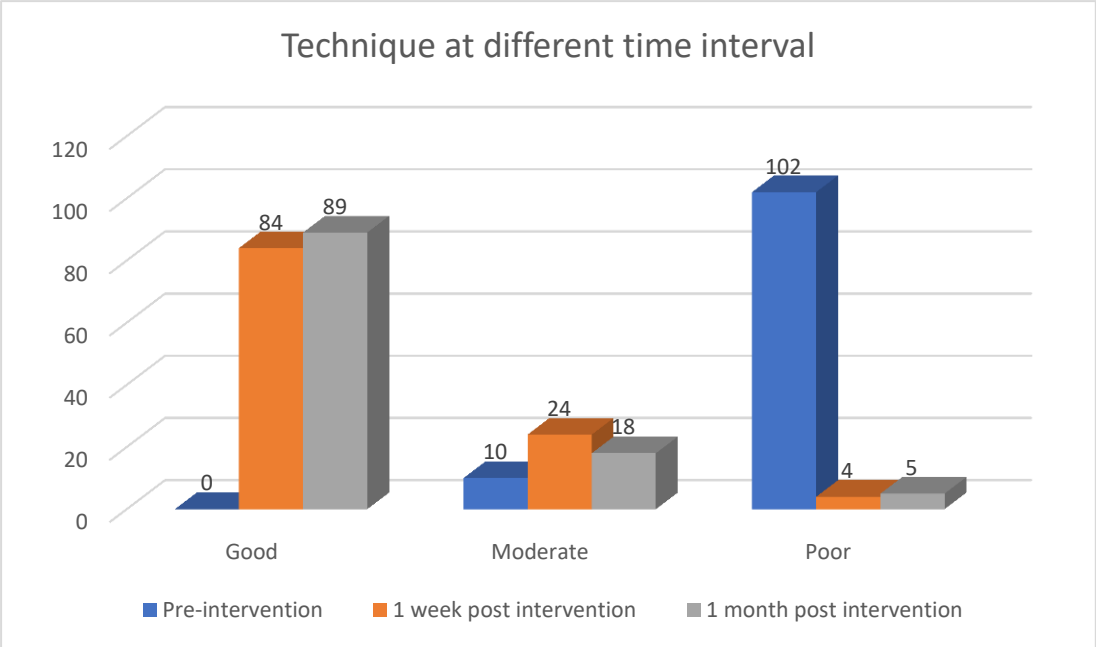
	Pre-intervention	Post 1 week intervention	Post 1 months intervention
Mean	2.473	7.473	7.196
Median	2.000	7.000	7.000
Std. Deviation	1.0566	1.0566	.8472
Minimum	1.0	6.0	5.0
Maximum	4.0	9.0	9.0
p-value (Anova test)	0.0001		
p-value (compare to pre-intervention, paired t-test)		0.0001	0.0001



The mean ALWORAFI score increased from 2.47 pre-intervention to 7.47 after 1 week and slightly declined to 7.20 after 1 month. The median score improved from 2.00 to 7.00 across the same intervals. The scores demonstrated significant statistical improvement from baseline at both 1-week and 1-month follow-ups (p=0.0001).

Table 10: Comparison of technique at different time interval

Technique	Pre-intervention		1 week post intervention		1 month post intervention	
	n	%	n	%	n	%
Good	0	0	84	75.0	89	79.5
Moderate	10	8.9	24	21.4	18	16.1
Poor	102	91.1	4	3.6	5	4.5
p-value (Anova test)	0.0001					
p-value (compare to pre-intervention-Paied t-tes)			0.0001		0.0001	



Before intervention, poor technique was observed in 102 participants (91.1%), moderate technique in 10 (8.9%), and none demonstrated good technique. After 1 week, 84 participants (75.0%) exhibited good technique, 24 (21.4%) had moderate technique, and 4 (3.6%) still had poor technique. At 1 month, 89 participants (79.5%) had good technique, 18 (16.1%) had moderate technique, and only 5 (4.5%) continued to show poor technique. The improvement in inhaler technique over time was statistically significant.

DISCUSSION

DISCUSSION

Asthma is one of the most common chronic respiratory conditions affecting children worldwide, characterized by reversible airway obstruction, bronchial hyper-responsiveness, and inflammation. Effective asthma management involves both pharmacological therapy and proper inhalation technique, particularly the use of metered dose inhalers (MDIs) with or without spacers. Despite the widespread use of MDIs, incorrect technique remains a significant barrier to optimal asthma control, especially among children. Poor inhaler technique results in inadequate drug delivery, persistent symptoms, frequent exacerbations, and increased healthcare utilization. Studies have shown that structured educational interventions can significantly improve inhaler technique and overall asthma outcomes. The AL-WORAFI criteria provide a standardized approach to assess and score inhaler technique objectively. In rural and resource-limited settings, education is often underutilized in asthma care. Therefore, evaluating the impact of educational strategies tailored to children and caregivers becomes crucial. This study aimed to assess the effect of a simple yet structured educational intervention on inhaler technique, symptom control, and AL-WORAFI scores in children aged 6–18 years diagnosed with asthma. By targeting early behavioral changes and enhancing understanding of proper inhaler use, this intervention could serve as a sustainable model for asthma management in pediatric populations, particularly in low-resource or underserved areas.

Age and Gender Distribution

In our study, the mean age of participants was 11.97 years with a standard deviation of 3.91 years, ranging from 6 to 18 years. The age distribution was relatively uniform across three age categories: 36.6% were between 6-10 years, 36.6% were between 11-15 years, and 26.8% were older than 15 years. This balanced distribution across childhood and adolescence provides a comprehensive view of asthma management techniques across different developmental stages.

Regarding gender distribution, our study included 57 males (50.9%) and 55 females (49.1%), showing a nearly equal representation with only a slight male predominance. This balanced gender distribution strengthens the generalizability of our findings across both male and female pediatric asthma patients.

When comparing our demographic profile with existing literature, notable differences emerge. Abegaz TM et al. (2020) [56]conducted their study on adult patients with a mean age of 51.77 years (±15.40), which is significantly older than our pediatric population. Their gender distribution showed a female predominance (55.4%), which differs slightly from our nearly equal gender distribution with a small male predominance.

Roopavathy GM et al. (2023) [55]did not explicitly report the age and gender distribution of their participants in the available abstract, making direct demographic comparisons challenging. Similarly, Carvalho Coelho AC et al. (2016) [57]conducted a literature review including 5,879 participants across 17 studies but did not provide specific demographic breakdowns in the abstract, though they noted that their review focused on children and adolescents, making their target population comparable to ours.

Nalini GK et al. (2016)[58] and Jolly GP et al. (2015) [59] focused on different populations altogether—medical students and general participants respectively—rather than asthmatic children, which limits direct demographic comparisons.

The pediatric focus of our study is particularly important given that asthma often begins in childhood, and establishing proper inhaler technique early can have long-term implications for disease management. The balanced age distribution across childhood and adolescence in our study allows for insights into how educational interventions might need to be tailored for different developmental stages, a consideration that adult-focused studies like Abegaz TM et al. (2020) [56] cannot address.

However, it's worth noting that the pediatric focus may present unique challenges in terms of comprehension and coordination abilities, which might influence the effectiveness of educational interventions compared to adult populations. The nearly equal gender distribution in our study is advantageous for generalizability, as it minimizes potential gender-related biases in the assessment of educational intervention effectiveness.

Residence and Environmental Factors

Our study found that a majority of participants (67.0%) resided in rural areas, while 33.0% were from urban settings. This predominance of rural participants is important to consider when interpreting our results, as rural residents might face different challenges in asthma management compared to their urban counterparts, including access to healthcare resources, environmental exposures, and possibly educational background.

Regarding environmental factors, only 10.7% of our participants reported exposure to allergens, 10.7% had a family history of asthma, and 7.1% had a history of passive smoking. These relatively low rates of known risk factors suggest that our study population might have had fewer exacerbating factors for their asthma compared to other populations.

In contrast, Abegaz TM et al. (2020) [56] reported that the majority of their participants (60.3%) resided in urban areas, which is the opposite of our population distribution. This fundamental difference in residence patterns could influence factors such as access to healthcare education, exposure to pollution, and socioeconomic factors that might affect inhaler technique and adherence.

The other comparative studies did not explicitly report the residence patterns or environmental factors of their participants in the available abstracts, limiting direct comparisons. However, Carvalho Coelho AC et al. (2016) [57] noted that most of the studies in their review were from developed countries, which might suggest a predominance of urban participants with potentially different environmental exposures compared to our largely rural cohort.

The predominance of rural participants in our study highlights the importance of developing educational interventions that are effective and accessible in rural settings, where healthcare resources and educational opportunities might be more limited. This becomes particularly relevant when considering the substantial improvement in inhaler technique observed in our study, suggesting that well-designed educational interventions can be effective even in predominantly rural populations.

The low rates of reported allergen exposure, family history of asthma, and passive smoking in our study population are noteworthy. These factors are generally considered risk factors for asthma development and exacerbation. The low prevalence in our cohort might suggest either underreporting due to awareness limitations or genuinely lower exposure in our specific population. This could potentially influence the baseline severity of asthma and consequently the response to improved inhaler technique.

Symptom Control and Its Improvement

One of the most significant findings of our study was the dramatic improvement in symptom control following educational intervention. Pre-intervention, 63.4% of participants had poorly controlled symptoms, 36.6% were partially controlled, and none were well controlled. After just one week post-intervention, this pattern shifted considerably, with 36.6% achieving well-controlled symptoms, 55.4% partially controlled, and only 8.0% remaining poorly controlled. By the one-month follow-up, an impressive 86.6% of participants had well-controlled symptoms, 9.8% were partially controlled, and only 3.6% remained poorly controlled. This improvement was statistically significant ($p=0.0001$).

This substantial improvement in symptom control aligns with findings from several comparative studies. Carvalho Coelho AC et al. (2016) [57] reported in their literature review that educational interventions resulted in a 29% reduction in asthma symptoms among children and adolescents, along with decreases in hospitalizations, emergency visits, and school absenteeism. While our study did not specifically measure these outcomes, the dramatic improvement in symptom control would likely translate to similar benefits.

Abegaz TM et al. (2020) [56] approached the relationship between inhaler competency and symptom control from a different angle, noting that only 5.5% of their participants achieved well-controlled asthma, and incompetence in MDI use was a significant factor reducing asthma control (AOR of 0.168). This inversely supports our finding that improving inhaler technique leads to better symptom control.

Roopavathy GM et al. (2023) [55] did not explicitly report on symptom control outcomes in the available abstract, focusing instead on knowledge and technique improvements. Similarly, Nalini GK et al. (2016) [58] and Jolly GP et al. (2015)[59] focused primarily on technique improvement rather than clinical outcomes, as they were conducted with medical students and general participants rather than asthma patients.

The rapid improvement in symptom control observed in our study—with significant changes evident after just one week—suggests that improper inhaler technique may be a substantial barrier to effective asthma management. The continued improvement at one month, with 86.6% achieving well-controlled status, indicates that the benefits of educational intervention are sustained and potentially enhanced over time as patients continue to practice and refine their technique.

This finding has profound clinical implications, suggesting that a relatively simple and cost-effective educational intervention can dramatically improve clinical outcomes in pediatric asthma patients. The magnitude of improvement—from zero patients with well-controlled symptoms pre-intervention to 86.6% at one month—highlights the critical importance of proper inhaler technique in asthma management and the substantial impact that focused education can have.

ALWORAFI Score Improvement

Our study utilized the ALWORAFI score to assess inhaler technique, and the results showed significant improvement following educational intervention. The mean score increased from 2.47 pre-intervention to 7.47 after one week, then slightly declined to 7.20 after one month. The median score improved from 2.00 to 7.00 across the same intervals. This improvement was statistically significant ($p=0.0001$) and indicates substantial enhancement in inhaler technique following education.

When comparing our findings with existing literature, several parallels emerge despite differences in assessment tools. Roopavathy GM et al. (2023) [55] reported that correct MDI usage improved from 25% pre-intervention to 62% post-intervention ($P < 0.0001$), showing a similar pattern of significant improvement, though the magnitude appears somewhat less than in our study.

Nalini GK et al. (2016) [58] used the National Asthma Education and Prevention Program (NAEPP) criteria and found that skill demonstration scores increased from 3.78 ± 1.06 pre-intervention to 7.37 ± 1.67 post-intervention. This improvement is remarkably similar to our findings, where scores increased from approximately 2.5 to 7.2-7.5, suggesting consistency in the impact of educational interventions across different assessment tools and populations.

Jolly GP et al. (2015) [59] reported that median scores for inhaler technique increased from 3 at baseline to 6, 7, and 8 after the first, second, and third educational sessions, respectively, with a slight drop to 7 at one-month follow-up. This pattern closely mirrors our findings, including the slight decrease at one month (from 7.47 to 7.20 in our study), suggesting that some skill degradation over time is common and might necessitate reinforcement sessions.

The similarity in score improvements across these different studies, despite variations in population, setting, and assessment tools, strengthens the evidence for the effectiveness of educational interventions in improving inhaler technique. The consistent finding of significant improvement across studies suggests a robust effect that transcends specific methodological approaches.

The slight decline in ALWORAFI scores from one week to one month in our study (7.47 to 7.20) deserves consideration. This minor regression might indicate that some participants began to revert to old habits or forgot certain aspects of proper technique over time. Similar patterns were observed by Jolly GP et al. (2015), suggesting that this phenomenon is not unique to our study. This highlights the potential importance of refresher sessions or periodic reassessment to maintain optimal technique over the long term.

Despite this slight decline, it's important to note that the one-month scores still represented a dramatic improvement over baseline (2.47 to 7.20), indicating that the majority of the educational benefit was retained. This suggests that even a single educational intervention can have substantial and relatively durable effects on inhaler technique, though optimal results might require periodic reinforcement.

Technique of Inhaler Use

Our analysis of inhaler technique showed remarkable improvement following educational intervention. Pre-intervention, 91.1% of participants demonstrated poor technique, 8.9% moderate technique, and none showed good technique. After just one week, this pattern was dramatically reversed, with 75.0% exhibiting good technique, 21.4% moderate technique, and only 3.6% still showing poor technique. At the one-month follow-up, 79.5% had good technique, 16.1% moderate technique, and 4.5% poor technique. This improvement was highly statistically significant (p=0.0001).

This dramatic improvement aligns with findings from several comparative studies, though the magnitude of improvement in our study appears particularly substantial. Roopavathy GM et al. (2023) [55] reported an improvement in correct MDI usage from 25% to 62% following educational intervention, which, while significant, represents a smaller proportion achieving correct technique compared to our 79.5% with good technique at one month.

Abegaz TM et al. (2020) [56] found that only 18.2% of their participants demonstrated competency in MDI usage without intervention, highlighting the common problem of poor baseline technique. This is consistent with our finding that none of our participants demonstrated good technique at baseline.

Jolly GP et al. (2015) [59] reported that only one participant could perform all steps correctly at baseline, with significant improvement following education. This aligns with our finding of 0% good technique at baseline improving to 79.5% at one month, though their study did not report the final percentage achieving perfect technique.

The pattern of dramatic improvement in our study—from 0% to 75-79.5% with good technique—underscores the profound impact that targeted educational interventions can have on inhaler technique. This magnitude of improvement suggests that poor technique is largely attributable to insufficient education rather than inherent difficulties in using the devices, at least in the pediatric population studied.

The slight improvement in the percentage with good technique from one week (75.0%) to one month (79.5%) is interesting and differs somewhat from the pattern observed with ALWORAFI scores, which showed a slight decline over this period.

This might suggest that while some nuances of technique (captured in the continuous ALWORAFI score) might diminish slightly over time, the core competency (captured in the categorical assessment of technique as good/moderate/poor) remains robust or even improves with practice.

The small proportion still demonstrating poor technique at one month (4.5%) warrants attention, as these individuals might require additional or alternative educational approaches. This persistent subgroup with poor technique mirrors findings in other studies, such as Jolly GP et al. (2015),[59] which noted that not all participants achieved optimal technique even after multiple sessions. This highlights the importance of identifying and addressing factors that might impede learning in certain individuals, which could include cognitive, physical, or motivational barriers.

While our study focused on the overall impact of educational intervention rather than comparing different educational methods, several of the comparative studies provide valuable insights into the relative effectiveness of various approaches.

Nalini GK et al. (2016) [58] directly compared three educational methods—video clips, information leaflets, and physical demonstrations—and found that physical demonstration yielded the highest improvement. Scores following physical demonstration were significantly higher than for video and leaflet groups both at one week (8.8 vs. 7.2 and 6.1) and one month (8.25 vs. 7.1 and 5.7). This suggests that hands-on, interactive approaches might be more effective than passive information provision.

Similarly, Jolly GP et al. (2015) [59]compared written step-by-step instructions to physical demonstrations and found that the demonstration group showed significantly greater improvement in median scores (3.0 vs. 2.0). This again supports the superiority of interactive, visual learning for inhaler technique.

These findings have important implications for interpreting our results and designing future interventions. The substantial improvement observed in our study might be partly attributable to the specific educational approach used, and even greater improvements might be achievable by optimizing the educational methodology based on these comparative findings.

The consistent finding across studies that physical demonstration outperforms written or passive instruction aligns with educational theory regarding psychomotor skill acquisition. Inhaler use is fundamentally a psychomotor skill that benefits from observation, practice, and feedback rather than merely conceptual understanding. This suggests that educational interventions for inhaler technique should prioritize demonstration, practice opportunities, and corrective feedback rather than relying primarily on written or verbal instruction.

The potential importance of repeated sessions, as highlighted by Jolly GP et al. (2015),[59] who conducted multiple training sessions, also deserves consideration. While our study demonstrated substantial improvement after a single intervention, the slight regression in ALWORAFI scores from one week to one month suggests that refresher sessions might help maintain or further enhance technique. Jolly's finding that scores improved with each subsequent session supports this possibility.

Cultural and contextual factors might also influence the effectiveness of different educational approaches. Our predominantly rural population might respond differently to various educational methods compared to the urban populations or medical students studied in some of the comparative research. Future studies could explore whether the optimal educational approach varies based on demographic factors such as age, education level, or rural versus urban residence.

The findings from our study have several important clinical implications for pediatric asthma management. The dramatic improvement in both inhaler technique and symptom control following educational intervention suggests that proper technique education should be a standard component of asthma management for all pediatric patients using MDIs.

This aligns with Carvalho Coelho AC et al.'s (2016) [57] conclusion emphasizing "the importance of school-based educational programs in managing asthma effectively and reducing its overall burden among children and adolescents." Their finding that educational interventions led to a 35% decrease in hospitalizations and emergency visits further underscores the potential clinical and economic benefits of improved inhaler technique.

Abegaz TM et al.'s (2020) [56] identification of barriers to proper MDI use, including cost concerns (91.9%) and the misconception that medication should only be used for symptoms (90.2%), highlights the importance of addressing both technique and understanding in comprehensive asthma education. This suggests that optimal educational interventions should address both the "how" (technique) and the "why" (purpose and importance) of proper inhaler use.

The rapid improvement in symptom control observed in our study—with significant changes after just one week—suggests that technique education could provide a quick and cost-effective means of improving outcomes in poorly controlled pediatric asthma. This is particularly relevant in resource-limited settings, where optimizing the effectiveness of existing medications through proper technique might be more feasible than accessing newer or more expensive therapies.

The predominance of rural participants in our study suggests that these educational benefits are achievable even in settings that might have more limited healthcare resources. This is encouraging for the potential implementation of similar interventions in various rural communities globally.

However, the slight decline in ALWORAFI scores from one week to one month, despite maintained improvement in categorical technique assessment, suggests that periodic reinforcement might be necessary for optimal long-term results. This aligns with Jolly GP et al.'s (2015) [59] observation of score fluctuations over time and improvement with repeated sessions.

The small proportion of participants still demonstrating poor technique at one month (4.5%) indicates that standard educational approaches might not be effective for all patients. This subgroup might benefit from alternative or intensified educational strategies, or might face barriers beyond knowledge gaps, such as physical limitations or motivational factors.

CONCLUSION
&
RECOMMENDATIONS

CONCLUSION & RECOMMENDATIONS

Conclusion:

This study demonstrated that a structured educational intervention significantly improved the use of metered dose inhalers in asthmatic children aged 6 to 18 years, as measured by AL-WORAFI criteria. At baseline, the majority of children demonstrated poor inhaler technique, with over 91% falling in the "poor" category. One week following the intervention, a substantial shift was observed, with 75% achieving good technique, and this further increased to 79.5% at one-month follow-up. In parallel, symptom control showed marked improvement; poorly controlled cases declined from 63.4% at baseline to just 3.6% after one month, while well-controlled symptoms rose dramatically to 86.6%. Additionally, the AL-WORAFI scores showed a statistically significant improvement over time, supporting the effectiveness of the educational strategy. These findings highlight the critical role of education in pediatric asthma management, especially in enhancing device usage and symptom control. The intervention was simple, reproducible, and effective, making it suitable for widespread implementation in both urban and rural healthcare settings. Incorporating structured inhaler training into routine clinical care and school-based asthma programs may offer long-term benefits in reducing morbidity and improving quality of life in asthmatic children. Continued reinforcement and periodic re-education are recommended to sustain these improvements over time.

Strengths

1. Use of standardized assessment tool (AL-WORAFI criteria) to objectively measure inhaler technique
2. Longitudinal design with multiple follow-up points (one week and one month) to assess both immediate and sustained effects
3. Comprehensive assessment of both technical outcomes (inhaler technique) and clinical outcomes (symptom control)

Limitations

1. Lack of comparison between different educational approaches, unlike some comparative studies that evaluated various instructional methods (demonstrations vs. video vs. written materials)
2. No explicit measurement of healthcare utilization outcomes (hospitalizations, emergency visits) that might demonstrate economic benefits
3. Absence of control group to account for potential confounding factors or improvements due to repeated assessment rather than intervention

Recommendations

1. Implement standardized inhaler technique education as a core component of pediatric asthma management protocols, particularly in rural and resource-limited settings
2. Develop targeted strategies for the small subset of patients who continue to demonstrate poor technique despite standard education
3. Incorporate periodic reinforcement sessions to prevent skill degradation over time, as suggested by the slight decline in scores between one week and one month
4. Conduct comparative studies of different educational methodologies to identify optimal approaches, considering findings from other studies that physical demonstrations may be superior to passive instruction
5. Extend follow-up periods beyond one month to assess long-term maintenance of improved technique and symptom control
6. Include additional outcome measures in future research, such as healthcare utilization, school attendance, quality of life, and cost-effectiveness
7. Design studies with control groups to strengthen causal inferences about intervention effectiveness

Explore demographic, psychological, and environmental factors that might influence individual responses to educational interventions

SUMMARY

SUMMARY

Current study was prospective observational study conducted at the Paediatrics OPD and In Patient Department, Santosh Medical College and Hospital, Ghaziabad. This study was aimed to evaluate the effect of a structured educational intervention on the use of metered dose inhalers in asthmatic children aged 6 to 18 years, assessed using the AL-WORAFI criteria. A total 112 participants were included in the study. Summary of the findings are follow-

Age: The study included 112 asthmatic children with a mean age of 11.97 years (±3.91). The age range of participants was 6 to 18 years. When grouped, 41 children (36.6%) were between 6–10 years, 41 children (36.6%) were between 11–15 years, and 30 children (26.8%) were above 15 years of age.

Gender: Of the total participants, 57 (50.9%) were male and 55 (49.1%) were female, reflecting a nearly equal gender distribution with a slight male predominance.

Residence: Most of the children resided in rural areas, accounting for 75 participants (67.0%), while 37 participants (33.0%) belonged to urban settings.

Exposure to Allergens: Twelve participants (10.7%) reported exposure to known allergens, whereas the majority—100 participants (89.3%)—had no such exposure.

Family History of Asthma: A positive family history of asthma was noted in 12 participants (10.7%). The remaining 100 children (89.3%) had no reported family history of asthma.

History of Passive Smoking: Exposure to passive smoking was present in 8 children (7.1%), while 104 participants (92.9%) had no history of such exposure.

Symptom Control Over Time: Significant improvements in asthma symptom control were observed over time following the educational intervention. At baseline, 71 children (63.4%) had poorly controlled symptoms, while 41 (36.6%) were partially controlled, and none had well-controlled symptoms. One week after the intervention, 41 children (36.6%) showed well-controlled symptoms, 62 (55.4%) were partially controlled, and only 9 (8.0%) remained poorly controlled. After one month, well-controlled symptoms were seen in 97 children (86.6%), with 11 (9.8%) partially

controlled and just 4 (3.6%) still poorly controlled. These changes were statistically significant (p=0.0001).

AL-WORAFI Score Over Time: The AL-WORAFI score, reflecting inhaler use and symptom control, improved significantly over time. The mean score increased from 2.47 at baseline to 7.47 after one week and slightly decreased to 7.20 at one month. The median score also improved from 2.00 to 7.00. The difference in scores from baseline to both follow-up intervals was statistically significant (p=0.0001).

Inhaler Technique Over Time: Inhaler technique improved markedly following the intervention. Initially, 102 participants (91.1%) demonstrated poor technique, 10 (8.9%) showed moderate technique, and none displayed good technique. After one week, 84 children (75.0%) used the inhaler with good technique, 24 (21.4%) with moderate technique, and only 4 (3.6%) continued to have poor technique. At one month, the number of children with good technique rose to 89 (79.5%), moderate technique was seen in 18 (16.1%), and poor technique declined further to just 5 (4.5%). The improvement in inhaler usage technique over time was statistically significant (p=0.0001).

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ANNEXURES

PROFORMA

(ANNEXURE 1)

Patient Name:

Date:

Age/Sex:

Brief History and relevant clinical Findings:

Symptoms in last 4 weeks

1. Day time cough and or difficulty in breathing
   - Less than 2 times per week (Score-0)
   - More than 2 times per week (Score-1)
2. Night time cough and or difficulty in breathing.
   - None (Score-0)
   - Any night (Score-1)
3. Use of SABA (reliever medication)
   - Less than 2 time per week (Score-0)
   - More than two times per week (Score-1)
4. Limitation of activities due to cough and or breathlessness
   - Yes (Score-1)
   - No (Score-0)

DAYTIME

NIGHT

	COUGH	***LIMITATION OF ACTIVITY***	***USE OF SABA***	***SLEEP DISTURBED DUE TO COUGH***
	खाँसी	***सामान्य खेल कूद की सीमा***	***पंप की जरूरत***	***खांसी के कारण नींद टूटना***
Week 1 D1				
D2				
D3				
D4				
D5				
D6				
D7				
Score				
Week 2 D1				
D2				
D3				
D4				

D5				
D6				
D7				
Score				
Week 3 D1				
D2				
D3				
D4				
D5				
D6				
D7				
Score				
Week 4 D1				
D2				
D3				
D4				
D5				
D6				
D7				
Score				

Asthma controlled (SCORE=0)

Asthma Partly controlled (SCORE=1-2)

Asthma uncontrolled (SCORE= 3-4)

Technique of inhalation of medicine

• Proper

• Poor

Compliance of the medicine

• Good

• Poor Device of inhalation

• Good & maintained

• Needs change

Co-morbidities

• Allergic rhinitis

• Sinusitis

• Adenoid Hypertrophy

• Gastroesophageal reflux

• Depression & Anxiety

• Obesity

• Obstructive sleep apnea

Further action /management:

Home Management: In case of sudden onset of breathlessness, give 6 puffs of Asthalin-100 MDI at an interval of 2 minutes and then wait for 20 minutes. In case of no improvement, repeat 6 puffs of Asthalin-100 MDI in the same manner and wait for 20 minutes. If no improvement, repeat 6 puffs of Asthalin-100 MDI again in same manner. If improvement: Repeat Asthalin-100 MDI 2-4 hourly for next 2-3 days and continue control medicine as prescribed. If no improvement at this stage: immediately go to hospital.

Next date of visit

Sign

INFORMED CONSENT

(ANNEXURE 2)

Subject Identification No. for study:

Title of the Study: **The Impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria**

Name of the Principal Investigator: Dr. Sumedha Chaudhary

I have received the information sheet on the above study and have read and / or understood the written information. I have been given the chance to discuss the study and ask questions. I consent for my ward to take part in the study and I am aware that this participation is voluntary. I understand that I may withdraw my ward at any time during the study. I understand that the information collected about my ward from participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to those records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

_____ _____

Signature with Name Date

For queries contact Dr. Sumedha Chaudhary (+917774036134)

INFORMED CONSENT

(ANNEXURE 3)

अवगतसहमतिफार्म

इस परीक्षण के लिए विषय पहचान संख्या:

परियोजना का शीर्षक: **The Impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria**

भ्रूण-मातृ परिणाम का एक तुलनात्मक अध्ययन,

प्रधान अन्वेषक का नाम : Dr. Sumedha Chaudhary

मुझे अध्ययन पर सूचना पत्र प्राप्त हुआ है और मैंने लिखित जानकारी को पढ़लिया है / समझलिया है। मुझे अध्ययन पर चर्चा और सवाल पूछने का मौका दिया गया है। मुझे जानकारी है कि मेरी भागीदारी स्वैच्छिक है, और मुझे अध्ययन में भाग लेने के लिए सहमति है।

मुझे जानकारी है मैं सहमति किसी भी समय वापस ले सकता हूँ। मुझे जानकारी है कि मेरी भागीदारी से मेरे बारे में एकत्रित की गई जानकारी और मेरे चिकित्सा नोटों के वर्गों को जिम्मेदार व्यक्तियों द्वारा देखा जा सकता है (नैतिकता समिति के सदस्यों / नियामक अधिकारियों) ।मैं अपने रिकॉर्ड का उपयोग करने के लिए इन व्यक्तियों को सहमति देता हूँ।

मुझे जानकारी है कि मुझे रोगी सूचना पत्रक की और सहमति पत्रकी एक प्रतिदी जाएगी।

_____ _____

हस्ताक्षर व नाम दिनांक

For queries contact Dr. Sumedha Chaudhary (+917774036134)

PATIENT INFORMATION SHEET

(ANNEXURE 4)

Patient's name:

Study Subject No.:

Background to the study: I, Dr. Sumedha Chaudhary, MD Pediatrics post graduate, am conducting a study "The Impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria". This study will help in determining the factors influencing the age of menarche in adolescent girls.

Enrolment in the study: Participation in the study is on a voluntary basis. The subject be given treatment for asthma as this is a cross sectional study. Your ward may volunteer to participate in this study after you (the parent) have signed the written informed consent form. Once enrolled, your details will be filled in the proforma. These details will be used while compiling the result. You may leave the study at any point of time if you so desire. If you choose to opt out of the study during any point of time, your details will not be used. This is an absolutely safe study. There is no risk involved per se.

ETHICAL CLEARANCE LETTER

(ANNEXURE 5)

SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

F. No. SU/R/2023/2489[32] Dated: 26.09.2023

Subject: Grant of Ethical Clearance for **Thesis Protocol** Topic "**The impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria",** submitted by **Dr. SUMEDHA CHAUDHARY,** MD/MS student of Batch 2022-2023, Department of **PAEDIATRICS**.

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **"The impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-18 years) using al-worafi criteria", Dr. SUMEDHA CHAUDHARY** is informed that the **Thesis Protocol** submitted by him/her was considered by the **Screening Committee** of the Santosh Medical College & Hospital in its meetings held on 17.07.2023 to 28.07.2023. The recommendations of the **Screening Committee** were considered in detail by the **Institutional Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee**.

He /She is informed accordingly for further necessary action.

[Dr. NARESH SHARMA]
REGISTRAR

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, U.P.

Dr. SUMEDHA CHAUDHARY
MD/MS student of batch 2022-2023
Department of PAEDIATRICS
Email: sumedhash@yahoo.co.in

Copy to:

1. The Vice Chancellor
2. The Dean, SMC&H
3. The Dean – Academics
4. The Dean – Research
5. The Director - IQAC
6. Dr. Veenu Agarwal (Guide)
7. HOD of PAEDIATRICS

ANNEXURE 6

Table 1: Recommended Checklist of Metered-Dose Inhaler (MDI).[3,4,8]

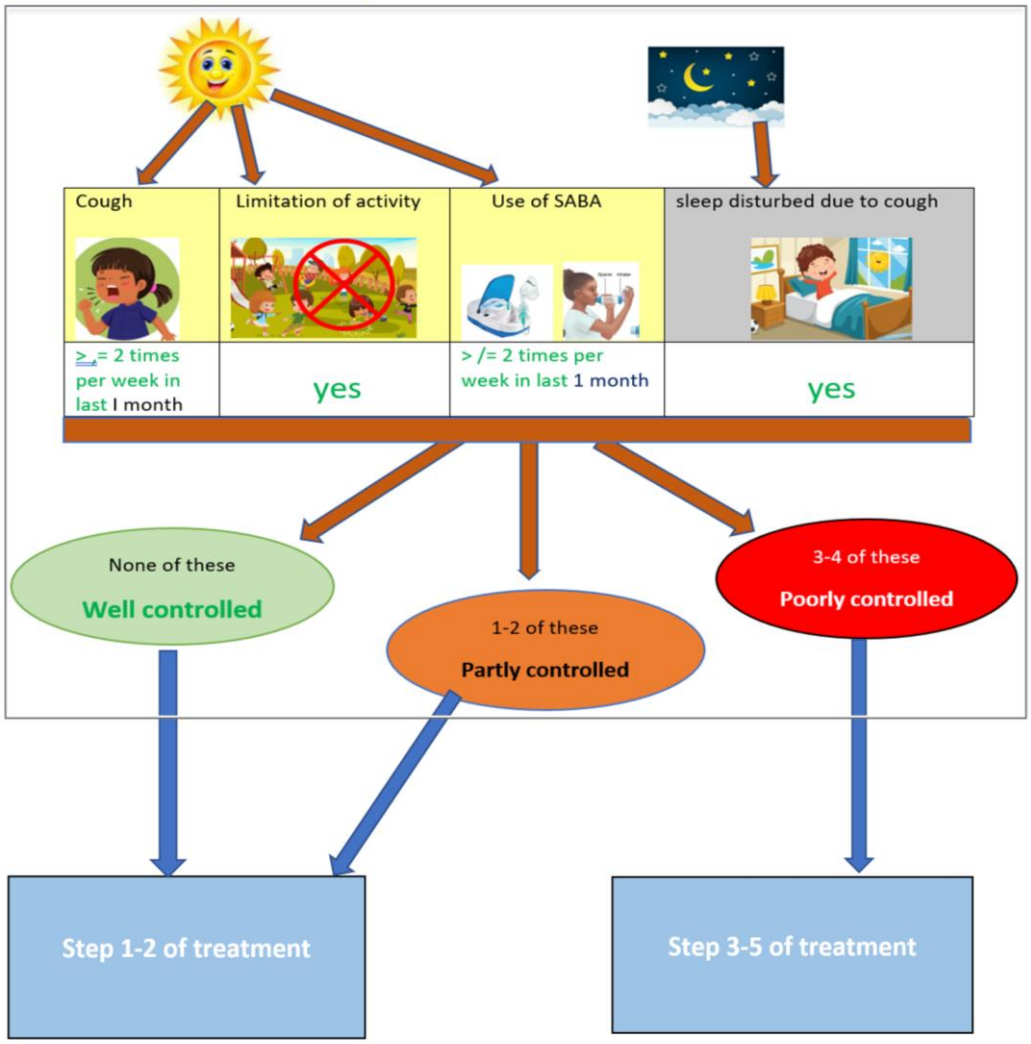
	Step	Score
1	**Shake the inhaler well.**[a]	
2	**Remove the dust cap.**[a]	
3	Exhale slowly through pursed lips.	
4	If using the "closed-mouth" technique, hold the inhaler upright and place the mouthpiece between your lips. Be careful not to block the opening with your tongue or teeth. If using the "open-mouth" technique, open your mouth wide and hold the inhaler upright 1–2 inches from your mouth, making sure the inhaler is properly aimed.	
5	**Press down on the inhaler once as you start a slow, deep inhalation.**[a]	
6	Continue to inhale slowly and deeply through your mouth. Try to inhale for at least 5 s.	
7	Hold your breath for 10 s (use your fingers to count to 10 slowly). If 10 s makes you feel uncomfortable, try to hold your breath for at least 4 s.	
8	Exhale slowly.	
9	Wait at least 30–60 s before inhaling the next puff of medicine.	

[a] Critical steps.

ANNEXURE 7

Asthma symptom control Chart

in **adolescent**s & children **6–11 years:**



PLAGIARISM REPORT

(ANNEXURE 8)

Dr. Sumedha Chaudhary

The Impact of Educational intervention on the use of metered dose inhaler in asthmatic children (6-1

Santosh University, Ghaziabad

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16th February 2025

Certificate Of Participation

Is presented to Dr Sumedha Chaudhary

For his/her participation as a faculty/ delegate/ in

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Dean and Professor, SMCH Ghaziabad

Mahalakshmi

Dr. Mahalakshmi, V.N
Vice Chancellor

MASTER CHART

MASTER CHART

							Preintervention		Post-1 week		post-1 months	
S.N	AGE	GENDER	Residence	Exposure to any allergen	family history of asthma	history of passive smoking	ALWORAFI	symptoms (1- well controlled, 2-partly controlled, 3-poorly controlled	ALWORAFI	symptoms (1- weel controlled, 2-poor controlled, 3-poorly controlled	ALWORAFI	symptoms (1- well controlled, 2-partly controlled, 3-poorly controlled
1	12	M	R	No	No	No	3	2	8	1	7	2
2	15	M	U	No	No	No	2	3	7	2	9	3
3	11	M	R	Y	No	No	3	3	8	2	7	3
4	11	F	R	No	No	No	2	3	7	2	7	3
5	13	M	R	No	No	No	1	2	6	1	5	3
6	15	F	U	No	Yes	No	3	2	8	1	7	3
7	7	F	U	No	No	No	2	3	7	2	8	3
8	18	M	R	No	No	No	4	3	9	2	8	3
9	7	F	U	No	No	No	2	3	7	2	7	3
10	12	M	R	No	No	No	4	2	9	1	8	3
11	18	F	R	No	No	No	2	3	7	2	7	3
12	7	M	R	Y	No	No	3	3	8	2	7	3
13	15	M	U	No	No	No	3	3	8	2	7	3

14	18	F	R	No	Yes	No	3	2	8	1	8	3
15	7	M	U	No	No	No	2	3	7	2	7	3
16	11	M	R	No	No	No	2	2	7	1	6	3
17	17	F	U	No	No	No	3	3	8	2	8	3
18	18	F	R	No	No	No	2	3	7	2	7	3
19	7	M	R	No	No	Yes	4	2	9	1	7	3
20	11	M	R	No	No	No	2	2	7	1	6	2
21	7	M	U	No	No	No	1	3	6	2	7	3
22	18	F	R	Y	No	No	3	3	8	2	8	3
23	6	F	R	No	No	No	3	2	8	1	8	3
24	16	M	U	No	No	No	2	3	7	2	7	3
25	6	M	R	No	No	No	4	3	9	2	9	3
26	9	F	R	No	No	No	2	3	7	2	7	3
27	15	F	R	No	No	No	3	2	8	1	8	3
28	16	M	U	No	Yes	No	1	2	6	1	6	2
29	8	F	R	Y	No	No	4	3	9	2	9	3
30	14	M	U	No	No	No	1	3	6	2	6	3
31	8	F	R	No	No	No	2	3	7	2	7	3
32	8	F	R	No	No	No	4	2	9	1	7	3
33	13	M	R	Y	No	No	1	3	6	2	6	3
34	7	F	R	No	No	Yes	2	3	7	2	7	3
35	12	M	R	No	Yes	No	3	3	8	2	7	3
36	8	F	U	No	No	No	1	2	6	1	6	2
37	10	M	R	No	No	No	2	3	7	2	7	3
38	17	M	R	No	No	No	1	2	6	1	6	2

39	14	F	U	No	No	No	2	3	7	2	7	3
40	7	M	R	Y	No	No	4	3	9	2	8	3
41	12	M	R	No	No	No	1	2	6	1	6	3
42	9	F	R	No	Yes	No	2	2	7	1	7	3
43	8	F	R	No	No	No	2	3	7	2	7	3
44	16	M	R	No	No	Yes	4	3	9	2	8	3
45	13	M	U	No	No	No	3	2	8	1	8	3
46	14	M	R	No	No	No	2	3	7	2	8	3
47	17	F	U	No	No	No	4	3	9	2	8	3
48	17	F	R	No	No	No	3	3	8	2	8	3
49	10	M	R	No	No	No	2	2	7	1	6	3
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51	8	M	U	No	No	Yes	1	3	6	2	7	3
52	7	F	R	No	No	No	3	3	8	2	7	3
53	15	M	R	Y	Yes	No	3	3	8	2	7	2
54	6	F	U	No	No	No	3	2	8	1	8	3
55	10	M	R	No	No	No	1	3	6	2	7	3
56	15	F	R	No	No	No	4	3	9	2	7	3
57	16	F	R	No	No	Yes	3	3	8	2	7	3
58	11	M	U	No	No	No	3	2	8	1	8	3
59	12	F	R	No	No	No	4	3	9	2	7	3
60	8	M	R	No	No	No	2	2	7	1	7	3
61	6	F	R	No	Yes	No	2	3	7	2	7	3
62	11	M	U	No	No	No	3	3	8	2	8	3
63	13	M	R	No	No	No	1	2	6	1	6	3

64	11	F	R	No	No	No	2	2	7	1	7	3
65	8	M	R	No	No	No	1	3	6	2	6	2
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99	16	M	U	No	Yes	No	4	3	9	2	7	3
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